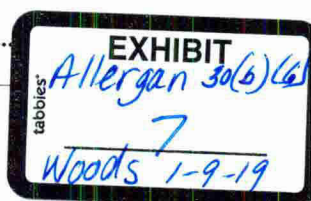# EXHIBIT 505

A Watson Pharma, Inc.

Call Center Operations
Licenses Administrator Operational Procedure

PROCEDURE:	License Maintenance Create, Change License or Create, Change Listing/Exclusion for Controlled and Non-Controlled substance License		
Written by:	Karen Schomer	Date:	05/03/04
Call Center Policy Number:	OPDLA 507200-01.08	Policy Effective Date	May 3, 2004
Revision written by:	Larry Shaffer Mary Moskello	Revision date:	April 04, 2007
CTM Transaction:	VX01N- License Create VX02N- License Change VB01- Create Listing / Exclusion VB02- Change Listing / Exclusion VE30- Existing Licenses VE31- License Blocked Sales Orders VCH1- Create Batch Search Strategy VCH2- Change Batch Search Strategy	CTM Doc #	
Prerequisites SAP Transaction Code	VD01- Create Customer VD02- Change Customer		
Post requisites SAP Transaction Code			

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Woods 1-9-19

A Watson Pharma, Inc.

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Licenses Administrator Operational Procedure

PROCEDURE:	Create, Change or Create Listing/Exclusion for Controlled and Non-Controlled substance License		
Revision Number:	OPDLA 507200-01.08	Effective Date:	May 5, 2004
Revision Written By:	Larry Shaffer Mary Moskello	Revision Date:	April 04, 2007
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Call Center Operations
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PROCEDURE:	Create, Change or Create Listing/Exclusion for Controlled and Non-Controlled substance License		
Revision Number:	OPDLA 507200-01.08	Effective Date:	May 5, 2004
Revision Written By:	Larry Shaffer Mary Moskello	Revision Date:	April 04, 2007
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Purpose

Establish and maintain the proper method of applying licensing information on an account to ensure compliance with the Drug Enforcement Administration (DEA) licensing requirements and the Prescription Drug Marketing Act (PDMA), as well as, the National Association of Boards of Pharmacy.

Scope

All Call Center Operations employee directly or indirectly responsible for customer account maintenance

Procedure

Once a customer account has been opened, updated, or unblocked, the Customer Master Administrator will submit the account maintenance form, along with the SAP account number to the Licensing Administrator. The licensing information should be reviewed and verified for accuracy.

All information necessary for analysis, review and validation of a license must be submitted to the SAP Licensing Administrator.

The following information is verified against the current License for accuracy:

1. Customer Name

2. Ship-To Address

   Note: Ship-to address MUST match the License, however PDMA regulations policy to ship non-controlled sample products only to a facility that the requesting practitioner operates from. If the address of the licensed practitioner does not match the address of the practitioner's license. The License Administrator must obtain a copy of a voided Rx and/or a letter of authorization from the physician as proof that this is a facility the practitioner is operating from.

3. DEA number / State License

4. DEA expiration date / State License expiration date

5. Approved Drug Schedule(s)

Please take note: Accounts are not deleted or de-activated. When an account is no longer in use, i.e. per customer request, location has moved, or any other reasons, Customer Master will block the account and the License Administrator will expire all current licenses attached to the account.

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A. DRUG SUBSTANCES – Controlled:

1. DEA License

DEA license is required for orders containing controlled substances. The DEA license includes the DEA license number, DEA license expiration date and the approved drug schedules (2, 2N, 3, 3N, 4, 5).

Schedule	Regulatory Definitions
2	High Potential for abuse. Use may lead to severe physical or psychological dependence. No renewals are permitted
2N	*Same as above except, Non-narcotic*
3	Some potential for abuse. Use may lead to low to moderate physical dependence or high psychological dependence. Up to 5 renewals are allowed within 6 months.
3N	*Same as above except, Non-narcotic*
4	Low potential for abuse. Use may lead to limited dependence either physically or psychologically. Up to 5 renewals are permitted within 6 months.
5	Subject to state and local regulation. Abuse potential is low; a prescription may not be required.
Rx	Prescription *(SAP requirement)*

Verification of the DEA license number, DEA shipping address, and DEA expiration date and drug schedule can be made by:

a. Using The U.S. Department of Commerce National Technical Information Services (NTIS) Drug Enforcement Administration (DEA) website: http://deanumber.com/ (See Exhibit B).

b. Obtaining a photocopy of the DEA license certificate from the customer or on the website DEA.com.

If copy received from the customer does not exist according to the DEA website or the DEA license has expired, the SAP Licensing Administrator will leave the order on license block in SAP, until the appropriate documentation is received. The SAP Licensing Administrator will contact the customer or the CSR responsible for the account to request a photocopy of the DEA License. The License Administrator will update the account upon receipt of a valid DEA license to remove the block on the order in SAP. The SAP Licensing Administrator will also communicate and report back to the Customer Support department on the licensing status, if necessary.

If the photocopy of the DEA License is not received, the Licensing Administrator will contact the customer or the CSR responsible for the account a second time requesting the photocopy of the DEA license. If the photocopy of the DEA license is not received, the customer will be notified that the pending order will be cancelled until a valid DEA license is received. The License Administrator will communicate with the Customer Master to update the account with an overall

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block until a valid license has been received. Once a valid license has been received the overall block will be removed.

*NOTE: A Wholesaler, Distributor, Exporter and Importer may file a "straight" II. This provision allows a registrant to register for only a class 2 schedule, but entitles the registrant to receive both 2 and 2N schedules. All other schedules (3, 3N, 4, 5) must be registered to receive shipment. Also, customers with a DEA license automatically receive schedule Rx.

Retail Outlets and Practitioners must register all schedules to receive shipment.

The check digit algorithm will determine the validity of a DEA number. The seventh digit of the DEA number is the Check Digit. Add the first, third, and fifth digits to equal SUM1. Add the second, fourth, and sixth digits and then multiply by 2 for Sum2. Add SUM1 + SUM2. The last digit of this total should equal the seventh (Check Digit) of the DEA #.

Note: On occasion DEA licenses with only 1 letter at the beginning (i.e. R10184159) may be submitted. These licenses are usually submitted by customers that have a name that starts with a number (i.e. 212 Pharmacy). The check digit algorithm can still be used by treating the first number as the 2nd letter of a typical DEA license. If necessary, the DEA can be called directly to verify the validity of a license.

DEA check digit algorithm

For example: DEA License RW0184159

DEA	First	Second	Third	Fourth	Fifth	Sixth	Seventh (check digit)	Results	
RW	0		8		1		9	9	Sum1
		1		4		5		10 x 2 = 20	Sum2

2. <u>Creating Exclusion Record</u>

The only time a customer material exclusion is set up is when the customer requests to exclude schedules. The customer may request to exclude schedules because the facility does not have proper storage and/or when the customer does not wish to receive those schedules. When creating exclusions, if there is a need to delete schedule numbers, the entire line must be selected and the delete icon must be used.

3. <u>Violations</u>

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The License Administrator will review and release sales orders pending licensing verification. This is critical in order to remain in compliance with the DEA, State and PDMA law as it pertains to the sales and distribution of pharmaceutical products.

*NOTE: On a monthly basis, the DEA registration file information is loaded, by the Information Systems group. The updated information is in accordance with information on file at the DEA. This is inclusive of DEA license expiration date and authorized schedules. However, the DEA registration file information may not be as current as the DEA website mentioned above. The most current data should be used. Please see the Information Systems group update process below:

Monthly DEA License Update from NTIS CD Process

1. **CD received via mail by Call center in Corona CA** – generally, the update CD for a particular month arrives anywhere from the 15th to the 25th of that month.

2. **Call Center notifies SAP SD Production Support** – Prod Support picks CD from Call Center.

3. **Prod Support executes a trial run in a test system** – this is not done to update the license values in the test system, rather to determine whether there are any format or data problems with the CD. In the past 14 months we have had circumstances in which a) dates on the CD were incorrectly formatted and b) schedule values on the CD were not valid (licenses with Schedule 1). It is important to discover these errors and request a replacement CD from NTIS prior to using the CD to update the production system.

4. **Prod Support executes the custom License Update program in the production system** – a brief summary of the functionality of the program:

Custom Program Name: ZVI_DEA_LICENSE
Transaction Code: ZVLICUPD

The program selects all active DEA license records from the SAP system. Each record is then matched against the NTIS CD using DEA number, if found, the End Dates and schedules of the SAP license and the NTIS entry are compared. If they are identical, no updates are made in SAP. If they are different (i.e., new End Date, different schedules), the existing SAP license is expired and a new license is created using the values from the NTIS entry. If a match is not found, the SAP license is expired, as the validity of the license could not be confirmed from the NTIS CD.

The program also dumps the full content of the NTIS CD into a custom SAP table ZVDEA for reference purposes. After completion of the job, the number of records in this table is compared to documentation received with the CD to confirm that the record counts match. This is done via transaction code ZVDEA.

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If errors occur during the execution of the job, Prod Support will analyze and correct the errors. The job is usually executed Friday evening, so that errors can be resolved with limited impact to the business.

5. **Post Processing Reporting** – after processing is complete, Prod Support produces a listing of Expired and new licenses, using the SQVI Quickviewer query tool in SAP. The listing shows all licenses expired; and. if a new license was created (in the case of updates). This listing is sent to the License Team for review.

Notes: one issue regarding this process is that a time lag will always potentially exist between receipt/application of the CD and the actual status of the DEA licenses. The Licensing team has access to daily updated information on DEA licenses via the internet, including newly created licenses; they will capture and create/update licenses in the SAP system based on business requirements. However, as noted in the processing summary, if the CD does not contain a license (i.e., perhaps a license just created/approved in the past week, after the latest CD was mailed), the program will consider it invalid.

The Post Processing listing also contains information about the Created On date and Created by ID of a license. One possibility is for the License Team to review the list by the Created On date, so that expired licenses that were created most recently will be readily apparent. These are the most likely to have been created/updated after the CD was issued, and the License Team can manually update them before any business impact is realized. If the license continues to be missing from the CD month after month (requiring manual re-creation), this should be researched; supposedly. if it's not on the CD it's doesn't exist.

Licenses used on specific orders: this is not related to the update process in any way; however, this data is available via standard SAP transaction ENGK, using the Assigned Documents option under Alert Reporting. Among the search criteria available are license type, license number (internal SAP or external/DEA number), Sold-to customer and schedule number.

4. Licensing Issues

Whenever there is a discrepancy between the information on the licensing website and the account, for example, the customer has recently moved to another address, but the website still reflects the old address. The Customer Service Representative should then contact the customer to verify the correct information and obtain the supporting documents. If the account needs to be changed, the Customer Service Representative will need to fill out the appropriate form and forward to the Customer Master group. If the Customer Master group cannot update the address on the account within 24 hrs, then the Licensing group should EXPIRE the current license. Once the Customer Master group has followed their procedure to correct the address in SAP then the licensing group will validate the license according to standard procedures. If the customer has a new license number, then the current license should be expired immediately and a new license should be created according to standard procedures.

Validating Medical Prescriber's State Licenses

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The License Administrator will validate the State License using the IMS website. Once the license has been faxed it will be printed for record retention. The License Administrator will create the license to reflect the IMS data.

In the event IMS is not up to date, the License Administrator can visit the respective state website and print a copy for record retention. If the state website and IMS reflect an expired license, the customer will need to provide an updated license.

If the state website reflects a valid license, but IMS reflects an expired license, a web inquiry will be submitted to IMS for validation. Once the validation is received from IMS, then the license can be created and the order released.

Exception: If the order is for Trelstar or an Indigent and the state website shows a valid license, then the license can be created and the order released using the state website printout. A web inquiry with IMS is still needed, but the order will not be held until the IMS validation is received.

5. Health Identification Number (HIN)

If the HIN is being used, the Contracts Department need only submit the HIN. No additional documentation is required. The License Administrator will populate the current date in the "valid from" field and 12/31/9999 in the "valid to" field. On the ExpContrClass tab there is no need to include schedule numbers when creating a HIN, this field will be left blank. On the Customers tab, the License Administrator will need to add the customer account number and then accept the license under the Status tab. Input the SAP internal license number on the spreadsheet provided by the Customer Master Group. Once all the HIN numbers have been created the updated spreadsheet needs to be forwarded to the Customer Master Group.

6. License blocks

The License Administrator will be responsible to ensure that pending sales orders on hold due to license violations are investigated. Once the investigation has been completed the License Administrator will take the appropriate action necessary to either release the sales order hold or notify the appropriate Order Entry representative regarding the necessary action required in order to update the license. For example, if the order went to License Block (VE31) and we noticed that the customer cannot receive 2 and 2N on their license, the Licensing group would notify the CSR responsible for that account (and Order Processing, if necessary) that the customer is not able to receive the product they ordered. This usually happens when it is an EDI order or sample order.

7. CII Schedule Drugs and SOMS blocks

SOMS – Suspicious Order Monitoring System (Of Control Drugs Substances)
The License Administrator will be responsible to ensure that pending sales orders on hold due to suspicious order violations (SOMS) are investigated. The License Administrator will execute VA05 to determine the value and priority of the orders blocked due to SOMS violations. An Order Processing Representative or

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License Administrator will print the SOMS Form. The SOMS form contains Class of Trade (COT) averages and customer allowable/order and customer allowable/month.

The License Administrator will review the SOMS form to determine if customer contact is necessary. If customer contact is necessary, the License Administrator will contact the customer. If necessary, the customer contact information can be obtained from the CSR responsible for the account. The Licensing Administrator will contact the customer to confirm the quantity ordered. The customer will determine whether to: reduce the quantity, cancel the order, or provide a valid reason for the increase in order quantity or frequency.

The following procedure is used to identify if the order is at or over the allowance Watson gives the customer which will determine if the customer needs to be contacted.

Put the number that's in the "Order Quantity" column into the "Release Qty" column. Then, mathematically ADD the following columns "MTD Qty" plus the "Release Qty" to give you a total order quantity to date.

- If the "MTD Qty" plus the" Release Qty" is equal to or less than the "Customer allow/mth, then the reason code is "12" (Administration Release Customer Call Not Required).

- If the "MTD Qty" plus the "Release Qty" is greater than the "Customer Allow/mth , then the reason code is "01" (Increased Supply to new or existing customer/patient) and the customer should be contacted to obtain the reason for the increase. Reason code "01" (Increased Supply to new or existing customer/patient)", must have a 2nd signature of Supervisor level or above and a note containing the reason for the increase in order quantity or frequency.

- If the customer is called, the License Administrator will attach a note to the SOMS form which will include the customer contact name, phone number, reason for the increase in order quantity or frequency, and the SKU/Material number and description of the product released. If the same SKU/Material suspends again in the same month, the License Administrator will attach a copy of the original resolution to the SOMS investigation form. This process is for the current month and will need to be repeated at the start of each month.

Once this SOMS form is confirmed and verified, the License Administrator will release the SOMS violation block. Otherwise, the License Administrator will escalate the suspicious order (SOMS) to the next level. If the suspicious order (SOMS) gets to the point that DEA contact is necessary, then the License Administrator will contact the Watson Director, Controlled Substance Compliance. The Watson Director, Controlled Substance Compliance will contact the DEA.

Also please make note of the following:

- The 'Release Qty' column on the SOMS form will need to be filled in by the License Administrator; this is the quantity that the License Administrator releases. Usually the 'Release Qty' is the same as the 'Order Qty', unless the customer requests to reduce or cancel the order.

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- If the customer decides to reduce or cancel the order, the Licensing group will notify the CSR responsible for that account (and Order Processing, if necessary) that the customer has decided to reduce or cancel the order.

- If the customer decides to reduce the order quantity, the order may come off of SOMS violation hold automatically once the change has been made. If the order appears on the VA05 list after the change, then the License Administrator will need to evaluate the SOMS form again per standard procedures. Also if the customer decides to cancel the order, then the order may come off of SOMS violation. The License Administrator will need to execute the VA05 again to verify the order is not on the VA05 list.

- Class 2 and 2N's are filed in a separate filing cabinet. The DEA requires all Class 2 and 2N's to be filed separately from the 3, 3N, 4 and 5. All SOMS are filed by the account name, account number, City and State, by most current date. If within the same day there are multiple SOMS, then the most current Sales Document number is filed on top.

  Also, there are four states Kansas, Kentucky, New York and Rhode Island which DO NOT allow CONTROLLED samples sent to ANY practioners.

B. DEA License Renewal Maintenance:

At the beginning of the month, the License Administrator will use the "custlist" to find DEA licenses that are due to expire before the month end. The license Administrator will contact each customer to obtain a valid/updated DEA license. If the customer does not have a DEA license with an updated expiration date, then the DEA license in SAP will be expired on the expiration date shown in SAP. If updated DEA license is not received, the pending orders will be cancelled until a valid DEA license is received. The License Administrator will communicate with Customer Master to update the account with an overall block until a valid license has been received. Once a valid license has been received, the overall block will be removed and the license will be updated and the customer can re-submit any orders.

C. License for One Time Customer:

The Customer Master group will create a one-time customer master template (shell) only once, as necessary. This shell will be used to create orders for one-time customers. A one-time customer shell will be used by order processing to create orders for situations where a permanent customer master record is not needed, such as Tradeshows or Replacement Orders. A One-time customer shell SHOULD NEVER be used for any site order or control substance order. A Customer Master account must be set up in order to place these order types. These templates do not include entry of financial (company-level) data; as such, its usage should be restricted to free of charge orders (i.e., samples, literature etc.). If the one-time customer shell is used to generate a sales order, this record will supply basic customer master information and requires the order processing user to input key fields (i.e., name, address etc). The Licensing group will create the appropriate license for a one-time customer and link the license to the one-time ship-to customer's sales order.

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D. Unlicensed Locations:

If a representative receives an order for prescription drugs for an unlicensed location, he/she must fax a Letter of Authorization (see Exhibit A) to a responsible licensed individual who will accept responsibility for non-controlled substance prescription (RX) drugs being shipped to that specific location.
Such customers may include:
- Dialysis Centers
- Universities
- Health Organizations
- Clinics
- Humanitarian Aid
- Family Planning/Planned Parenthood

Regardless of whether a doctor/Medical Director/Mid-Level Practitioner license address is the same as the facility or ship to address, a properly filled out Letter of Authorization is required.

In the event the Letter of Authorization is submitted with a Mid-Level Practitioner's license, the Licensing Administrator will verify that the Mid-Level practitioner is able to received Rx product by reviewing the Buzzeo PDMA quarterly spreadsheet by logging into the Dendrite website, State Monitor section.

Note: A Letter of Authorization is valid for one year only.   Customer's Letters of Authorization can be found in the portal.

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E. Methamphetamine Control Act:

The License Administrator will create a virtual "MethAct" license in the format of MA and the business entity phone number (i.e. MA6029992002). Material Classification Rx prescription should be entered on the ExpContrClass tab. The License Administrator will "redetermine" the sales order (unblock) to the newly created MethAct license and the sales order will be released for delivery.

The License Administrator will check sales order document flow (VA03 Display Sales Order) to confirm a delivery document has been generated. The License Administrator will "Expire" the newly created MethAct license(s) once the order has shipped, usually the day after the license has been created. This will ensure a validation process is in place for future orders.

F. Indigent Accounts:

Quarterlies (As of 4/2007, DaVita Healthcare is the only customer of this sort)
> These customers place orders on a quarterly basis and the account should be created in the clinic's name. These clinics staff multiple physicians and seldom have their own licensees so licenses are generally linked at the order level, referencing the physician placing the order. A Letter of Authorization is needed as usual, and they are valid for one year. In the unlikely event that a clinic has its own license, the license may be linked at the customer master level.

Dailies
> These customers place orders on a daily basis and the account should be created in the physician's name, even if his office is located in a hospital or clinic. If the physician wants to ship goods to numerous locations, a Sold-To should be created for the primary location and Ship-To's should be created for the additional locations. All accounts are to be linked to the same state license even if the address does not match the license as long as this does not violate PDMA regulations. Note: The Sold-To address is usually the address that is on the physician's state license, but the physician may choose not to ship goods to the address listed on the state license, in this case the physician will choose another address as the Sold-To. If, at a later time, the physician wants to ship goods to the address listed on the state license, that account may be created as a Ship-To and linked to the existing Sold-To.

Trelstar and Indigents

- **Trelstar and Indigent orders are top priority and should be released as soon as possible following standard procedures.**

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ALLERGAN_MDL_03952785

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Papsure Physician Address Changes:

NOTE: You do not need a license for Papsure orders, since the Material master record considers Papsure as an OTC product, therefore, the order should not be held up for a license.

G. R&D Research and Development:

Shipments for prescription items to facilities for research and/or development purposes do not require licensing.

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Exhibit A – Unlicensed Location (Letter of Authorization)

WATSON PHARMA ®

Date:
Account:

To: Watson Pharma

Attn:

Phone:

Fax:

I hereby authorize Watson Pharma, Inc. to ship orders of pharmaceuticals directly

to: _____

located at: _____

Utilizing my **State license number** _____

I am affiliated with the clinic and direct the use of pharmaceutical products in it.

By: _____

Print Name: _____

Title: _____

State License Address: _____

City/State: _____

Date: _____

****Note: If the doctor is no longer affiliated with the facility or does not authorize shipment of prescription drugs, he/she is required to notify the person named above at Watson Pharma, immediately.****

360 Mt. Kemble Avenue, P.O. Box 1953 Morristown, NJ 07962-1953·Tel :(973)-355-8300 ·Fax 800-760-9224·Web Site.

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08/29/06
E.David

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Exhibit B - NTIS National Technical Information Services

In Joint Venture with

NT⬦S
U.S. Department of Commerce
National Technical Information Service
One Source. One Search. One Solution.

HOME | DEA SEARCH | ONLINE REGISTRATION | CSA DATABASE | LIST2 DATABASE | DEA API | ABOUT US | Login

SUBSCRIBER LOGIN

> USERNAME:
> PASSWORD:

LOGIN

Forgot your password?

DEA1 through DEA20

Password

VeriSign
SECURE SITE
CLICK TO VERIFY

This is the Official DEA Authorized Database

Drug Enforcement Administration (DEA) Controlled Substances Act Database Subscription Products

This is the official site to search these two important DEA databases.

Controlled Substances Act (CSA) Registration Database

The Latest update : March 11, 2004

The *Controlled Substances Act (CSA) Registration Database* consists of records of individuals registered under the Controlled Substances Act including registrants doing business under their individual name rather than a business name. These records are used to credential the CSA status of health practitioners as well as organizations.

LATEST NEWS:

NTIS and GIM.net Announce Re-Launch of deanumber.com

NTIS and Global Internet Management created deanumber.com as a service to quickly and easily confirm DEA Registration numbers. The site contains a fully searchable database of all persons and organizations certified to handle controlled substances under the Controlled Substances Act of 1970.

Now, deanumber.com has been redesigned and upgraded based on GIM.net's premiere Content Management Software,

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A   Watson Pharma, Inc.

Call Center Operations
Licenses Administrator Operational Procedure

PROCEDURE:	Create, Change or Create Listing/Exclusion for Controlled and Non-Controlled substance License		
Revision Number:	OPDLA 507200-01.08	Effective Date:	May 5, 2004
Revision Written By:	Larry Shaffer Mary Moskello	Revision Date:	April 04, 2007
			Page 17 of 20

Exhibit B – NTIS continued…

Drug Enforcement Administration (DEA)
Controlled Substance Act Registration Information
Online Search - As of March 11, 2004

Enter Search Criteria:

List Type [Active ▼]

DEA # [ ]

Business Activity Code [Search All ▼]

Business Sub Activity Code [Search All ▼]

Expiration Date [▼] [▼] [▼]

Company / Doctor Name [ ] [Beginning of the field ▼]

State [▼]

Zip [ ]

Enter a:
DEA # or
Zip or
State and Zip or
Company / Doctor Name

[Search]   [Reset]

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A Watson Pharma, Inc.

Call Center Operations
Licenses Administrator Operational Procedure

PROCEDURE:	Create, Change or Create Listing/Exclusion for Controlled and Non-Controlled substance License		
Revision Number:	OPDLA 507200-01.08	Effective Date:	May 5, 2004
Revision Written By:	Larry Shaffer Mary Moskello	Revision Date:	April 04, 2007
			Page 18 of 20

Exhibit B – NTIS continued…

DEA Number	Exp. Date	Company Name	State	Zip
AC0393734	8/31/2005	CITY PHARMACY INC	TN	37745
AT7665637	11/30/2005	SUSONG PHARMACY	TN	37745
BS0143850	2/28/2007	STUMM, HARRY J MD	TN	37745
BP3389093	3/31/2007	PATTERSON, MARK DAVID MD	TN	37745
MM0369365	1/31/2005	MCMILLIAN, JEFFREY OD	TN	37745
MR0852081	4/30/2005	ROBBINS, MELISSA A FNP	TN	37745
MM0467426	1/31/2006	MORRISON, REBECCA A PNP	TN	37745
MP0551033	3/31/2006	PACE, NANCY L NP	TN	37745
MC0649472	8/31/2006	CARRINO, THOMAS PA	TN	37745
BW8300220	5/31/2004	WALGREEN CO	TN	37745
BT4966288	11/30/2004	THE MEDICINE SHOPPE	TN	37745
AC0401202	12/31/2004	REVCO DISCOUNT DRUG CTRS, INC	TN	37745
AR8276405	12/31/2004	REVCO DISCOUNT DRUG CTRS, INC	TN	37745
BF8029589	9/30/2005	FOOD CITY PHARMACY #606	TN	37745
BH2489032	10/31/2005	HOWARD'S PHARMACY	TN	37745
BR3339618	6/30/2006	RITE AID OF TENNESSEE INC	TN	37745
BG8618689	9/30/2006	GREENE COUNTY DRUG STORE, LLC	TN	37745

Select the hyperlink that matches the DEA information you are searching for.

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A Watson Pharma, Inc.

Call Center Operations
Licenses Administrator Operational Procedure

PROCEDURE:	Create, Change or Create Listing/Exclusion for Controlled and Non-Controlled substance License		
Revision Number:	OPDLA 507200-01.08	Effective Date:	May 5, 2004
Revision Written By:	Larry Shaffer Mary Moskello	Revision Date:	April 04, 2007
			Page 19 of 20

Exhibit B – NTIS continued…

im.net

NTIS
National Technical Information Service

Current Date: 3/15/2004   **Data File Release Date:** March 11, 2004

Drug Enforcement Administration (DEA) Datafiles –Both

Registrant Profile

for

CITY PHARMACY INC

Address:	113 E CHURCH ST GREENEVILLE, TN 37745
State / Zip:	TN 37745
DEA Number:	AC0393734
Business Activity Code:	A
Drug Schedule:	22N 33N 4 5
Expiration Date:	8/31/2005

Print	Close

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A   Watson Pharma, Inc.

Call Center Operations
Licenses Administrator Operational Procedure

PROCEDURE:	Create, Change or Create Listing/Exclusion for Controlled and Non-Controlled substance License		
Revision Number:	OPDLA 507200-01.08	Effective Date:	May 5, 2004
Revision Written By:	Larry Shaffer Mary Moskello	Revision Date:	April 04, 2007
			Page 20 of 20

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WATSON PHARMACEUTICALS, INC.		SECTION:	011 Sales and Marketing
CORPORATE STANDARD OPERATING PROCEDURE			
DOCUMENT #: CSOP 011-004 REVISION #: 02		PAGE:	1 of 4
TITLE: Suspicious Orders of Controlled Drugs		EFFECTIVE DATE: 04/07/2009	

PURPOSE:

To assure distribution of controlled drugs is monitored for excessive use by an individual location using the DEA number as the identifier.

SCOPE:

This procedure applies to all controlled drugs distributed by Watson Laboratories, Inc. and its Subsidiaries.

DOCUMENT REFERENCES:

Document Number	Document Title
CTMAN 080-023-CC-OPR	Order Processing
CTMAN 080-045	License Entry and Maintenance

DEFINITIONS:

- DEA — Drug Enforcement Administration – A component of the Justice Department whose regulations enforce 21CFR, Part 1300 to end.

- SOMS — Suspicious Order Management System

PROCEDURE:

Responsibility	Action	
	1.0	**Process for Suspicious Orders of Controlled Drugs**
General	1.1	The SAP system compiles a past history of controlled substance drug product orders by each customer to establish a normal order size and order frequency. This is accomplished through the normal Sales Order process (see CTMAN 080-023-CC-OPR Order Processing, for details on this process).
Controlled Substance Compliance Management	1.2	The Controlled Substance Compliance Department determines the SOMS Multiplier Table.
	1.2.1	See CTMAN 080-045, License Entry and Management for description of system functionality with regards to the establishment of SOM levels, as well as how to access this information.

EXHIBIT
tabbies
Allergan 30(b)(6)
8
Woods 1-9-19

Printed: Wednesday, May 13, 2009 13:36:52

ALLERGAN_MDL_03641386

WATSON PHARMACEUTICALS, INC.	SECTION:	011 Sales and Marketing
CORPORATE STANDARD OPERATING PROCEDURE		
DOCUMENT #: CSOP 011-004 REVISION #: 02	PAGE:	2 of 4
TITLE: Suspicious Orders of Controlled Drugs	EFFECTIVE DATE:	04/07/2009

Responsibility	Action	
Master Data Administrator	1.3	If a processed order generates a SOMS excessive order flag in SAP (See CTMAN -80-023-CC- OPR, Order Processing), due to more frequent or larger than the normal order pattern, Master Data Administrator will generate a Suspicious Order Controlled Drug (SOMS)
	1.4	The Master Data administrator will review the SOMS report, and then, if warranted, contact the customer to confirm the quantity ordered and verify the reason for a larger or more frequent order.
	1.5	Once this SOMS report is confirmed and verified by the Customer, the SOMS report is signed and marked with a reason code by the Master Data Administrator and submitted to the Manager for review, and signature.
	1.6	The Master Data Administrator will be responsible to ensure that pending sales orders on hold due to suspicious order (SOMS) violation are investigated.
	1.7	The Master Data Administrator will release pending orders due to SOMS violations by canceling the order, or reducing the quantity, per SOMS procedure.
	1.8	If the SOMS violation cannot be resolved by canceling the order or reducing the quantity, the Master Data administrator will escalate the suspicious order to the next level.
Call Center Management	1.9	Determine if the order does or does not classify as suspicious.
	1.10	If a valid reason (based on objective criteria) does not exist, the order will be deemed as a suspicious order and will not be filled. Report suspicious issue to Control Substance Compliance Department.
Controlled Substance Compliance Department	1.11	The Control Substance Compliance Department will be responsible for reporting the order to the Drug Enforcement Administration.
Master Data Administrator	1.12	File a copy of the SOMS Report, along with the customer purchase order, in the suspicious order record file.

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WATSON PHARMACEUTICALS, INC.	SECTION:	011 Sales and Marketing
CORPORATE STANDARD OPERATING PROCEDURE		
DOCUMENT #: CSOP 011-004 REVISION #: 02	PAGE:	3 of 4
TITLE: Suspicious Orders of Controlled Drugs	EFFECTIVE DATE:	04/07/2009

CHANGE HISTORY:

Initiation / Change Control Number	Revision Number	Effective Date	Change Summary
C2004-0260	00	05/03/2004	New CSOP.

C2005-0317	01	09/19/2005	DEFINITIONS: DEA
			  "Agency" changed to "Administration".
			  "involve controlled substances, etc." changed to "enforces 21CFR, Part 1300 to end".
			1.3 Change Responsibility from "Order Processing Representative" to "License Administrator".
			1.4 "if warranted" added to action.
			1.11 "determine next level of communication" replaced with "be responsible for reporting the order to the Drug Enforcement Administration."
			1.12 Change Responsibility from "Order Processing Representative" to "License Administrator".

CHANGE HISTORY (in HotDox):

HotDox Workflow ID	Revision Number	Effective Date	Change Summary
CD-6798767	02	See effective date in header.	Change all reference of Licensing Administrator Title to : Master Data Administrator Change all reference of CTMAN 080-041-CC-OPR – to CTMAN 080-023-CC-OPR 1.2 The SOMS Multiplier Table is determined by the Controlled Substance Compliance Department. – Delete " Call Center Management" 1.3 "Order Processing will generate a Suspicious Order Controlled Drug (SOMS) report and email it to the License Administrator. – Change -Order Processing to Master Data Administrator – Delete" and email it to the License Administrator" 1.5 "the Supervisor or Management for review, and signature" Remove – Supervisor or.

ALLERGAN_MDL_03641388

	WATSON PHARMACEUTICALS, INC.	SECTION:	011 Sales and Marketing
	CORPORATE STANDARD OPERATING PROCEDURE		
	DOCUMENT #: CSOP 011-004 REVISION #: 02	PAGE:	4 of 4
	TITLE: Suspicious Orders of Controlled Drugs	EFFECTIVE DATE: 04/07/2009

UserName: Sandra Simmons (ssimmons)
Title: Mgr, Support Services
Date: Friday, 27 February 2009, 06:28 AM   Pacific Time
Meaning: I have authored this document.
==

UserName: Mary Woods (mwoods)
Title: Exec Dir, Call Center Operations
Date: Friday, 27 February 2009, 07:29 PM   Pacific Time
Meaning: I have reviewed and approved this document.
==

UserName: Marleah Martin (mmartin)
Title: Exec Dir, Corp Quality Assurance
Date: Tuesday, 03 March 2009, 08:35 AM   Pacific Time
Meaning: I have reviewed and approved this document.
==

UserName: Tracey Hernandez (tlherna)
Title: Dir, Controlled Substance Compliance
Date: Monday, 16 March 2009, 08:10 AM   Pacific Time
Meaning: I have reviewed and approved this document.
==

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PURPOSE:

To assure distribution of controlled drugs is monitored for excessive use by an individual location using the DEA number as the identifier.

SCOPE:

This procedure applies to all controlled drugs distributed by Watson Laboratories, Inc. and its Subsidiaries.
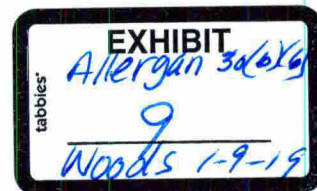
DOCUMENT REFERENCES:

Document Number	Document Title
CTMAN 080-023-CC-OPR	Order Processing
CTMAN 080-045	License Entry and Maintenance

DEFINITIONS:

- DEA   Drug Enforcement Administration – A component of the Justice Department whose regulations enforce 21CFR, Part 1300 to end.

- SOMS   Suspicious Order Management System

PROCEDURE:

Responsibility	Action

| | **1.0** | **Process for Suspicious Orders of Controlled Drugs** |

General   1.1   The SAP system compiles a past history of controlled substance drug product orders by each customer to establish a normal order size and order frequency. This is accomplished through the normal Sales Order process (see CTMAN 080-023-CC-OPR Order Processing, for details on this process).

Controlled Substance Compliance Management   1.2   The Controlled Substance Compliance Department determines the SOMS Multiplier Table.

         1.2.1   See CTMAN 080-045, License Entry and Management for description of system functionality with regards to the establishment of SOM levels, as well as how to access this information.

EXHIBIT

Allergan 3d(b)(6)

9

Woods 1-9-19

Responsibility	Action	
Master Data Administrator	1.3	If a processed order generates a SOMS excessive order flag in SAP (See CTMAN -80-023-CC- OPR, Order Processing), due to more frequent or larger than the normal order pattern, Master Data Administrator will generate a Suspicious Order Controlled Drug (SOMS)
	1.4	The Master Data administrator will review the SOMS report, and then, if warranted, contact the customer to confirm the quantity ordered and verify the reason for a larger or more frequent order.
	1.5	Once this SOMS report is confirmed and verified by the Customer, the SOMS report is signed and marked with a reason code by the Master Data Administrator and submitted to the Manager for review, and signature.
	1.6	The Master Data Administrator will be responsible to ensure that pending sales orders on hold due to suspicious order (SOMS) violation are investigated.
	1.7	The Master Data Administrator will release pending orders due to SOMS violations by canceling the order, or reducing the quantity, per SOMS procedure.
	1.8	If the SOMS violation cannot be resolved by canceling the order or reducing the quantity, the Master Data administrator will escalate the suspicious order to the next level.
Call Center Management	1.9	Determine if the order does or does not classify as suspicious.
	1.10	If a valid reason (based on objective criteria) does not exist, the order will be deemed as a suspicious order and will not be filled. Report suspicious issue to Control Substance Compliance Department.
Controlled Substance Compliance Department	1.11	~~The Control Substance Compliance Department will be responsible for reporting the order to the Drug Enforcement Administration.~~ Upon confirmation that the order is suspicious, the Control Substance Compliance Department will be responsible for reporting the order to the Drug Enforcement Administration and the applicable State Board of Pharmacy. Department of Regulatory Affairs will also report the incident to FDA within three business days.
Master Data Administrator	1.12	File a copy of the SOMS Report, along with the customer purchase order, in the suspicious order record file.

CHANGE HISTORY:

Initiation / Change Control Number	Revision Number	Effective Date	Change Summary
C2004-0260	00	05/03/2004	New CSOP.
C2005-0317	01	09/19/2005	DEFINITIONS: DEA "Agency" changed to "Administration". "involve controlled substances, etc." changed to "enforces 21CFR, Part 1300 to end". 1.3 Change Responsibility from "Order Processing Representative" to "License Administrator". 1.4 "if warranted" added to action. 1.11 "determine next level of communication" replaced with "be responsible for reporting the order to the Drug Enforcement Administration." 1.12 Change Responsibility from "Order Processing Representative" to "License Administrator".

CHANGE HISTORY (in HotDox):

HotDox Workflow ID	Revision Number	Effective Date	Change Summary
CD-6798767	02	~~See effective date in header.~~ 04/07/2009	Change all reference of Licensing Administrator Title to : Master Data Administrator Change all reference of CTMAN 080-041-CC-OPR – to CTMAN 080-023-CC-OPR 1.2 The SOMS Multiplier Table is determined by the Controlled Substance Compliance Department. – Delete " Call Center Management" 1.3 "Order Processing will generate a Suspicious Order Controlled Drug (SOMS) report and email it to the License Administrator. – Change -Order Processing to Master Data Administrator – Delete" and email it to the License Administrator" 1.5 "the Supervisor or Management for review, and signature" Remove – Supervisor or.
CD-8330136	03		Change to Section 1.11, Upon confirmation that the order is suspicious, the Control Substance Compliance Department will be responsible for reporting the order to the Drug Enforcement Administration and the applicable State Board of

			Pharmacy. Department of Regulatory Affairs will also report the incident to FDA within three business days.

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WATSON PHARMACEUTICALS, INC.	SECTION:	011 Sales and Marketing
CORPORATE STANDARD OPERATING PROCEDURE		
DOCUMENT #: CSOP 011-004 REVISION #: 04	PAGE:	1 of 5
TITLE: Suspicious Orders of Controlled Drugs	EFFECTIVE DATE: 07/19/2011	

PURPOSE:

To assure distribution of controlled drugs is monitored for excessive use by an individual location using the DEA number as the identifier.

SCOPE:

This procedure applies to all controlled drugs distributed by Watson Laboratories, Inc. and its Subsidiaries.

DOCUMENT REFERENCES:

Document Number	Document Title
CTMAN 080-045	License Entry and Maintenance
CTMAN 080-203	Order Processing

DEFINITIONS:

- DEA — Drug Enforcement Administration – A component of the Justice Department whose regulations.

- SOMS — Suspicious Order Monitoring System

PROCEDURE:

Responsibility	Action

1.0 Process for Suspicious Orders of Controlled Drugs

General 1.1 The SAP system compiles a past history of controlled substance drug product orders by each customer to establish a normal order size and order frequency. This is accomplished through the normal Sales Order process (see CTMAN 080-203 Order Processing, for details on this process).

DEA Affairs 1.2 The DEA Affairs Department determines the SOMS Multiplier Table.

   1.2.1 See CTMAN 080-045, License Entry and Management for description of system functionality with regards to the establishment of SOM levels, as well as how to access this information.

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WATSON PHARMACEUTICALS, INC.	SECTION:	011 Sales and Marketing
CORPORATE STANDARD OPERATING PROCEDURE		
DOCUMENT #: CSOP 011-004 REVISION #: 04	PAGE:	2 of 5
TITLE: Suspicious Orders of Controlled Drugs	EFFECTIVE DATE:	07/19/2011

Responsibility	**Action**	
Master Data Administrator	1.3	If a processed order generates a SOMS excessive order flag in SAP (See CTMAN 080-045, License Entry and Maintenance), due to more frequent or larger than the normal order pattern, Master Data Administrator will generate a Suspicious Order Monitoring System (SOMS) form.
	1.4	The Master Data administrator will review the SOMS form, and then, if warranted, contact the customer to confirm the quantity ordered and verify the reason for a larger or more frequent order.
	1.5	Once this SOMS form is analyzed, the SOMS form is signed and marked with a reason code by the Master Data Administrator and if necessary submitted to the Manager for review, and signature.
	1.6	The Master Data Administrator will be responsible to ensure that pending sales orders on hold due to suspicious order (SOMS) violation are investigated.
	1.7	The Master Data Administrator will release pending orders due to SOMS violations by releasing the order in full, canceling the order, or reducing the quantity, per SOMS procedure.
	1.8	If the SOMS violation cannot be resolved by research and justification, canceling the order or reducing the quantity, the Master Data administrator will escalate the suspicious order to the next level.
	1.9	If a valid reason (based on objective criteria) does not exist, the order will be deemed as an order of interest or a suspicious order and held for further review. Orders deemed as an order of interest or as suspicious, will be forwarded to the DEA Affairs Department for further review.
DEA Affairs	1.10	Upon confirmation that the order is suspicious, the DEA Affairs Department will be responsible for reporting the order to the Drug Enforcement Administration and the applicable State Board of Pharmacy. Department of Regulatory Affairs will also report the incident to FDA within three business days.
Master Data Administrator	1.11	File a copy of the SOMS form, along with any back up documentation, in the suspicious order record file.

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	WATSON PHARMACEUTICALS, INC.	SECTION:	011 Sales and Marketing
	CORPORATE STANDARD OPERATING PROCEDURE		
	DOCUMENT #: CSOP 011-004 REVISION #: 04	PAGE:	3 of 5
	TITLE: Suspicious Orders of Controlled Drugs	EFFECTIVE DATE:	07/19/2011

CHANGE HISTORY (before Livelink):

Initiation / Change Control Number	Revision Number	Effective Date	Change Summary
C2004-0260	00	05/03/2004	New CSOP.

C2005-0317	01	09/19/2005	DEFINITIONS: DEA
			    "Agency" changed to "Administration".
			    "involve controlled substances, etc." changed to "enforces 21CFR, Part 1300 to end".
			1.3 Change Responsibility from "Order Processing Representative" to "License Administrator".
			1.4 "if warranted" added to action.
			1.11 "determine next level of communication" replaced with "be responsible for reporting the order to the Drug Enforcement Administration."
			1.12 Change Responsibility from "Order Processing Representative" to "License Administrator".

CHANGE HISTORY (in Livelink):

Livelink Workflow ID	Revision Number	Effective Date	Change Summary
CD-6798767	02	04/07/2009	Change all reference of Licensing Administrator Title to : Master Data Administrator Change all reference of CTMAN 080-041-CC-OPR – CTMAN 080-023-CC-OPR. 1.2 The SOMS Multiplier Table is determined by the Controlled Substance Compliance Department. – Delete " Call Center Management" 1.3 "Order Processing will generate a Suspicious Order Controlled Drug (SOMS) report and email it to the License Administrator. – Change -Order Processing to Master Data Administrator – Delete" and email it to the License Administrator" 1.5 "the Supervisor or Management for review, and signature" Remove – Supervisor or.

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	WATSON PHARMACEUTICALS, INC.	SECTION:	011 Sales and Marketing
	CORPORATE STANDARD OPERATING PROCEDURE		
	DOCUMENT #: CSOP 011-004 REVISION #: 04	PAGE:	4 of 5
	TITLE: Suspicious Orders of Controlled Drugs	EFFECTIVE DATE:	07/19/2011

CHANGE HISTORY (in Livelink):

Livelink Workflow ID	Revision Number	Effective Date	Change Summary
CD-8330136	03	06/12/2009	Change to Section 1.11, Upon confirmation that the order is suspicious, the Control Substance Compliance Department will be responsible for reporting the order to the Drug Enforcement Administration and the applicable State Board of Pharmacy. Department of Regulatory Affairs will also report the incident to FDA within three business days.
CD-11129819	04	See effective date in header.	Changed: SOMS Report to SOMS Form Call Center to Customer Relations Controlled Substance Compliance Dept. to DEA Affairs 1.3 – CTMAN 80-023-CC OPR, Order Processing to CTMAN 080-045 License Entry & Maintenance; Suspicious Order Controlled Drug to Suspicious Order Monitoring System. Added: 1.5 – if necessary 1.7 – releasing the order in full 1.9 – an order of interest or a ; Orders deemed as an order of interest or as ; , will be forwarded to the 1.11 – any back up documentation Removed: 1.9 - Determine if the order does or does not classify as suspicious.

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WATSON PHARMACEUTICALS, INC.	**SECTION:**	**011 Sales and Marketing**
CORPORATE STANDARD OPERATING PROCEDURE		
DOCUMENT #: CSOP 011-004 REVISION #: 04	**PAGE:**	**5 of 5**
TITLE: Suspicious Orders of Controlled Drugs	**EFFECTIVE DATE: 07/19/2011**	

UserName: Larry E. Shaffer (lscheffe)
Title: Master Data Administrator
Date: Tuesday, 28 June 2011, 10:52 AM   Pacific Time
Meaning: I have authored this document.
==

UserName: Sandra I. Simmons (ssimmons)
Title: Mgr, Support Services
Date: Friday, 01 July 2011, 06:41 AM   Pacific Time
Meaning: I have reviewed and approved this document.
==

UserName: Marleah M. Martin (mmartin)
Title: Exec Dir, Corp Quality Assurance
Date: Monday, 11 July 2011, 01:07 PM   Pacific Daylight Time
Meaning: I have reviewed and approved this document.
==

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A Watson Pharma, Inc.

Call Center Operations
Master Data / License Admin. Operational Procedure

PROCEDURE:	License Maintenance Create, Change License or Create, Change Listing/Exclusion for Controlled and Non-Controlled substance License		
Written by:	Karen Schomer	Date:	05/03/04
Call Center Policy Number:	GUROPDLAR 507001.003	Policy Effective Date	May 3, 2004
Revision written by:	Larry Shaffer Mary Moskello Victoria Lepore	Revision date:	January 5, 2012
CTM Transaction:	VX01N- License Create VX02N- License Change VB01- Create Listing / Exclusion VB02- Change Listing / Exclusion VE30- Existing Licenses VE31- License Blocked Sales Orders VCH1- Create Batch Search Strategy VCH2- Change Batch Search Strategy	CTM Doc #	
Prerequisites SAP Transaction Code	VD01- **Create Customer** VD02- **Change Customer**		
Post réquisits SAP Transaction Code			

TABLE OF CONTENTS

Purpose

Establish and maintain the proper method of applying licensing information on an account to ensure compliance with the Drug Enforcement Administration (DEA) licensing requirements and the Prescription Drug Marketing Act (PDMA), as well as, the National Association of Boards of Pharmacy.

Scope

All Call Center Operations employees directly or indirectly responsible for customer account maintenance
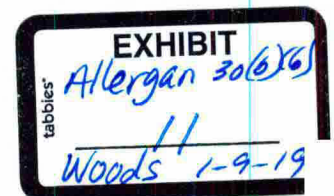
Procedure

Once a customer account has been opened, updated, or unblocked, the Master Data Administrator (MDA) will review and verify the licensing information for accuracy.

All information necessary for analysis, review and validation of a license must be submitted to the SAP Master Data Administrator (MDA).

The following information is verified against the current License for accuracy:

1. Customer Name
2. Ship-To Address

   Note: Ship-to address MUST match the DEA License. However PDMA regulations policy to ship non-controlled sample products only to a facility that the requesting practitioner operates from. If the address of the licensed practitioner does not match the address of the practitioner's license, then the MDA and/or CRA/SAA must verify that the practitioner does practice at the Ship-to address. Verification of the practitioner address may be done by obtaining a

A   Watson Pharma, Inc.

Call Center Operations
Master Data / License Admin. Operational Procedure

PROCEDURE:	Create, Change or Create Listing/Exclusion for Controlled and Non-Controlled substance License		
Revision Number:	GUROPDLAR 507001.003	Effective Date:	May 5, 2004
Revision Written By:	Larry Shaffer Mary Moskello Victoria Lepore	Revision Date:	January 5, 2012
			Page 2 of 12

copy of the doctor's valid state license, a phone call to the facility, finding the location on the internet via the yellow pages or comparable search engine, or avoided Rx that shows the practitioner at the Ship-to.

3. DEA number / State License

4. DEA expiration date / State License expiration date

5. Approved Drug Schedule(s)

Please take note: Accounts are not deleted or de-activated. When an account is no longer in use, i.e. per customer request, location has moved, or any other reasons, the MDA will block the account and expire all current licenses attached to the account. Also the MDA will report to the Board of Pharmacy, FDA and DEA in 3 business days if unable to authenticate the vendor/customer.

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A   Watson Pharma, Inc.

Call Center Operations
Master Data / License Admin. Operational Procedure

PROCEDURE:	Create, Change or Create Listing/Exclusion for Controlled and Non-Controlled substance License		
Revision Number:	GUROPDLAR 507001.003	Effective Date:	May 5, 2004
Revision Written By:	Larry Shaffer Mary Moskello Victoria Lepore	Revision Date:	January 5, 2012
			Page 3 of 12

A. DRUG SUBSTANCES – Controlled:

1. DEA License

DEA license is required for orders containing controlled substances. The DEA license includes the DEA license number, DEA license expiration date and the approved drug schedules (2, 2N, 3, 3N, 4, 5).

Schedule	Regulatory Definitions
2	High Potential for abuse. Use may lead to severe physical or psychological dependence. No renewals are permitted
2N	Same as above except, Non-narcotic
3	Some potential for abuse. Use may lead to low to moderate physical dependence or high psychological dependence. Up to 5 renewals are allowed within 6 months.
3N	Same as above except, Non-narcotic
4	Low potential for abuse. Use may lead to limited dependence either physically or psychologically. Up to 5 renewals are permitted within 6 months.
5	Subject to state and local regulation. Abuse potential is low; a prescription may not be required.
Rx	Prescription (SAP requirement)

Verification of the DEA license number, DEA shipping address, and DEA expiration date and drug schedule can be made by:

a. Using The U.S. Department of Commerce National Technical Information Services (NTIS) Drug Enforcement Administration (DEA) website: http://deanumber.com/ (See Exhibit A).

b. Obtaining a photocopy of the DEA license certificate from the customer or on the website DEANUMBER.com (NTIS).

If the copy received from the customer is not legible and does not exist on the DEA website (NTIS) or the DEA license has expired, the MDA will leave the order on license block in SAP, until the appropriate documentation is received. The MDA will contact the customer or the CRA responsible for the account to request a valid/current photocopy of the DEA License. The MDA will update the account upon receipt of a valid DEA license to remove the block on the order in SAP. The MDA will also communicate and report back to the Customer Support department on the licensing status, if necessary.

If the photocopy of the DEA License is not received, the MDA will contact the customer or the CRA responsible for the account a second time requesting the photocopy of the DEA license. If the photocopy of the DEA license is not received, the customer will be notified that the pending order will be cancelled until a valid DEA license is received. The MDA will update the account with an overall block until a valid license has been received. Once a valid license has been received the overall block will be removed.

*NOTE: Only the schedules (2, 2N, 3, 3N, 4, 5) that are registered and shown on the license will be created in SAP. Also, customers with a DEA license automatically receive schedule Rx.

Retail Outlets and Practitioners must register all schedules to receive shipment.

The check digit algorithm will determine the validity of a DEA number. The seventh digit of the DEA number is the Check Digit. Add the first, third, and fifth digits to equal SUM1. Add the second, fourth, and sixth digits and then multiply by 2 for Sum2. Add SUM1 + SUM2. The last digit of this total should equal the seventh (Check Digit) of the DEA #.

Note: On occasion DEA licenses with only 1 letter at the beginning (i.e. R10184159) may be submitted. These licenses are usually submitted by customers that have a name that starts with a number (i.e. 212 Pharmacy). The check digit algorithm can still be used by treating the first number as the 2nd letter of a typical DEA license. If necessary, the DEA can be called directly to verify the validity of a license.

DEA check digit algorithm									
For example: DEA License RW0184159									

DEA	First	Second	Third	Fourth	Fifth	Sixth	Seventh (check digit)	Results	
RW	0		8		1		9	9	Sum1
		1		4		5		10 x 2 = 20	Sum2

2. Creating Exclusion Record

Three exclusion methods are currently being used, Customer/Schedule Number, SalesDocType/Ord.reason/Sch No., and Customer/Material. The Customer/Schedule Number exclusion is set up is when the customer requests to exclude schedules. The customer may request to exclude schedules because the facility does not have proper storage and/or when the customer does not wish to receive those schedules. The SalesDocType/Ord.reason/Sch No. is setup when it is decided that a specific Order Type (i.e. Standard Order) and Order Reason (i.e. Drop ship) should not receive certain schedules. The Customer/Material is used the when specific materials will not be ordered/shipped to a specific customer.

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3. Violations

The Master Data Administrator (MDA) will review and release sales orders pending licensing verification. This is critical in order to remain in compliance with the DEA, State and PDMA law as it pertains to the sales and distribution of pharmaceutical products.

4. NTIS Disc

The Master Data Administrator (MDA) will download the NTIS file from the NTIS website on the first business day of the month; Go to www.DEA.NTIS.GOV

The link and the password for the following website will be on the portal
Go to www.DEA.NTIS.GOV
The screen will look as below:

Go to the "monthly file" link either to the left column or the bottom.

Click on the zipped format link.

Click once on the first file that starts with MA and ends with .zip
This brings up as sign on screen:

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ALLERGAN_MDL_01175577

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Connect to dea.ntis.gov   ? ×

The server dea.ntis.gov at DEA Monthly Access requires a
username and password.

User name: [ ]

Password: [ ]

☐ Remember my password

[OK]   [Cancel]

Enter the following information:
Username: 525246
Password: Watson! 2011
Checking the remember password is optional
Click OK

Save file anywhere, usually desktop
Go to the location where you saved it (usually desktop)
Right click on the file and click on extracting all, Click Next
Click OK (the default location is the desktop)
Click Finish
Now open the Customer Master folder and then the sub-folder NTIS File

- Customer Master
  - 1 Pending (Initial request)
  - 3 Pending (Accounting)
  - 4 Pending (Contracts)
  - 5 Pending (License)
  - 6 Pending (Notify requestor)
  - Accounting Completed 2004
  - CARS Tools
  - Compensation
  - Completed
  - CUSTLISTS
  - Drive Shortcuts
  - Licensing Department
  - MEMBERSHIP
  - MISC
  - NTIS File

Click on the location where you stored the recent NTIS file (usually desktop) and drag the file to the NTIS File folder.

Copy the path for this location as below:
V:\Sales Operations & Distribution\Customer Master\NTIS File

Send an email to the IT Dept along with the record count (found on the screen when you clicked on the "Monthly Files" on the original website). Make the subject of the email "NTIS File".

Once the file is loaded into SAP by the IT Dept., it will then be filed in Corona, CA with past NTIS Discs.

> *NOTE: On a monthly basis, the DEA registration file information is loaded, by the Information Systems group. The updated information is in accordance with information on file at the DEA. This is inclusive of DEA license expiration date and authorized schedules. However, the DEA registration file information may not be as current as the DEA website mentioned above. The most current data should be used. Please see the Information Systems group update process below:

> **Monthly DEA License Update from NTIS CD Process**

> 1. **Prod Support executes a trial run in a test system** – this is not done to update the license values in the test system, rather to determine whether there are any format or data problems with the CD. In the past 14 months we have had circumstances in which a) dates on the CD were incorrectly formatted and b) schedule values on the CD were not valid (licenses with Schedule 1). It is important to discover these errors and request a replacement CD from NTIS prior to using the CD to update the production system.

> 2. **Prod Support executes the custom License Update program in the production system** – a brief summary of the functionality of the program:

> **Custom Program Name:** ZVI_DEA_LICENSE
> **Transaction Code:**   ZVLICUPD

> The program selects all active DEA license records from the SAP system. Each record is then matched against the NTIS CD using DEA number, if found, the end dates and schedules of the SAP license and the NTIS entry are compared. If they are identical, no updates are made

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in SAP. If they are different (i.e., new end date, different schedules), the existing SAP license is expired and a new license is created using the values from the NTIS entry. If a match is not found, the SAP license is expired, as the validity of the license could not be confirmed with the NTIS file.

The program also dumps the full content of the NTIS file into a custom SAP table ZVDEA for reference purposes. After completion of the job, the number of records in this table is compared to documentation received with the file to confirm that the record counts match. This is done via transaction code ZVDEA.

If errors occur during the execution of the job, Prod Support will analyze and correct the errors. The job is usually executed Friday evening, so that errors can be resolved with limited impact to the business.

3. **Post Processing Reporting** – after processing is complete, Prod Support produces a listing of expired and new licenses, using the SQVI Quick viewer query tool in SAP. The listing shows all licenses expired; and, if a new license was created (in the case of updates). This listing is sent to the Master Data Team for review.

Notes: One issue regarding this process is that a time lag will always potentially exist between receipt/application of the CD and the actual status of the DEA licenses. The Licensing team has access to daily updated information on DEA licenses via the internet, including newly created licenses; they will capture and create/update licenses in the SAP system based on business requirements. However, as noted in the processing summary, if the CD does not contain a license (i.e., perhaps a license just created/approved in the past week, after the latest CD was mailed), the program will consider it invalid.

The Post Processing listing also contains information about the Created On date and Created by ID of a license. One possibility is for the Master Data Team to review the list by the Created on date, so that expired licenses that were created most recently will be readily apparent. These are the most likely to have been created/updated after the CD was issued, and the Master Data Team can manually update them before any business impact is realized. If the license continues to be missing from the CD month after month (requiring manual re-creation), this should be researched; supposedly, if it's not on the file it doesn't exist.

Licenses used on specific orders: this is not related to the update process in any way; however, this data is available via standard SAP transaction ENGK, using the Assigned Documents option under Alert Reporting. Among the search criteria available are license type, license number (internal SAP or external/DEA number), and Sold-to customer and schedule number.

5. Licensing Issues

Whenever there is a discrepancy between the information on the licensing website and the account, for example, the customer has recently moved to another address, but the website still reflects the old address. The Customer Relations Administrator should then contact the customer to verify the correct information and obtain the supporting documents. If the account needs to be changed, the CRA/ Specialty Account Administrator will need to fill out the appropriate form and submit according to standard procedures. If the Master Data group cannot update the address on the account within 48 hrs, then the Master Data group should EXPIRE the current license. Once the Master Data group has followed the procedure to correct the address in SAP then validate and re-instate the license according to standard procedures. If the customer has a new license number, then the current license should be expired immediately and a new license should be created according to standard procedures.

Validating Medical Prescriber's State Licenses

The Master Data Administrator will validate the State License using the PRS website.

In the event PRS is not up to date, the Master Data Administrator visits the respective state website. If the PRS and state website reflect an expired license, MDA will notify the CRA/SAA. The CRS/SAA will need to contact the customer to provide an updated license.

6. TIRF REMS REGISTRATION

The goals of the TIRF REMS Access Program are to mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors by:

- Prescribing and dispensing TIRF medicines only to appropriate patients, which includes use only in opioid-tolerant patients.
- Preventing inappropriate conversion between fentanyl products.
- Preventing accidental exposure to children and others for whom it was not prescribed.
- Educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose of TIRF medicines.

Effective March 12, 2012, Sold-to (corporate locations) making a direct purchase from the manufacturer are required to have a distributor registration in order to purchase and receive the following Fentanyl Citrate EQ Oral Trans sku's.

55253007430	FENTANYL CITRATE EQ ORAL TRANS 1200MCG30
55253007530	FENTANYL CITRATE EQ ORAL TRANS 1600MCG30
55253007030	FENTANYL CITRATE EQ ORAL TRANS 200MCG 30
55253007130	FENTANYL CITRATE EQ ORAL TRANS 400MCG 30
55253007230	FENTANYL CITRATE EQ ORAL TRANS 600MCG 30
55253007330	FENTANYL CITRATE EQ ORAL TRANS 800MCG 30

The registration is compliant for all of the SH locations associated with the Sold-to.

The Master Data Administrator (MDA) will access the **TIRF REMS Access Program** website **http://www.tirfremsaccess.com/TirfUISplashWeb/index.html** every Monday of each week.

Enter the following information:
Username:
Password:
Checking the remember password is optional???
Click OK???

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You will have access to the following tabs in the **TIRF REMS Access Program**:

- **Enrolled** – participants that are enrolled in the TIRF REMS Access program
- **Incomplete** – ignore this tab, not necessary to view
- **Deactivated** – customers opt out of the program
- **Choice of Pharmacy** – ignore this tab, not necessary to view
- **Distributor -)**

•

The participants that were enrolled in the Actiq/Fentora program will be grandfathered into the TIRF REMS ACCESS program,, they will be enrolled under the "distributor section" under the enrolled tab.

If the participant party opts outs , or does not register to participate in the TIRF REMS Access Program, you can locate the data under "distributor" **deactivated** tab.

When the customer's registration is within 90 days of expiration, they will receive notice for renewal. Verify the new effective dates at the "distributor section" under the enrolled tab.

There are different scenarios for the REMS program but not limited to:

- If there is a new SP that is participating in the REMS program, you need to create a REMS registration from the valid date of the registration and the valid to is good for two years from that point that the registration was received.

- You need to verify that there is true SH's at the Sold-to level that orders controls. Each SH must be a entity of the Corporate Office. For example, American Health Packaging and Testpak are repackagers and they shouldn't be included in the REMS registration.

- If the Sold-to no longer participates in the TIRF REMS Access Program, you need to expire the REMS registration and add notes in the comment field that SP is no longer participating in TIRF REMS Access Program. There is no need to add exclusions since the REMS registration will be expired.

- If an order is placed for a participant that is no longer in the program, the order will go on license block. You can verify by SH location, that there was a REMS registration and the comment notes will show the reason for the expired registration.

- If there is an order that goes on license block, you will need to check the **Legal Control Issue Error Log Item** to view the reason for the block. It could block be either for DEA or, State license and/or REMS registration. Look at the order and see what products are being ordered before going to the error log. If you notice it is Fentanyl products, than it is highly likely that it is due to a REMS registration issue.

- If the license block is for REMS, you need to search by SH location to see if there is a REMS registration and if there is, you need to check if the SH location was added to the registration.

- If the REMS registration is expired, you will need to contact the Customer Relations Administrator to handle.

NOTE: The external registration is "TIRFREMS" for all of the participating parties that have a REMS registration.

7. Health Identification Number (HIN)

If the HIN is being used, the Contracts Department need only submit the HIN. No additional documentation is required. The Master Data Administrator (MDA) will populate the current date in the "valid from" field and 12/31/9999 in the "valid to" field. On the ExpContrClass tab there is no need to include schedule numbers when creating a HIN, this field will be left blank. On the Customers tab, the MDA will need to add the customer account number and then accept the license under the Status tab. Input the SAP internal license number on the spreadsheet provided. Once all the HIN numbers have been created the updated spreadsheet needs to be forwarded to the Contracts Dept. if requested.

8. License blocks

The Master Data Administrator (MDA) will be responsible to ensure that pending sales orders on hold due to license violations are investigated. Once the investigation has been completed the MDA will take the appropriate action necessary to either release the sales order hold or notify the appropriate Order Entry representative regarding the necessary action required in order to update the license. If customer contact is necessary to obtain a valid license, the MDA will make an attempt to contact the customer to obtain a valid license. If the MDA is unable to obtain a valid license after contacting the customer, the MDA will notify the CRA/SAA and the CRA/SAA will contact the customer to obtain a valid license. For example, if the order went to License Block (VE31) and the MDA noticed that the customer cannot receive 2 and 2N on their license, the MDA would notify the CRA responsible for that account (and Order Processing, if necessary) that the customer is not able to receive the product they ordered. This usually happens when it is an EDI order or sample order. Note: For IMA customers, when an order is on VE31 and IMA block: and the MDA goes into the order to release it they will see a pop up message that states the order is on IMA block, do not make ANY changes. The MDA should back out of the order immediately and do not save any changes. The MDA must wait until the order is released from the IMA block before releasing the order from VE31 License Block; otherwise this will cause an error with the order. (IMA stands for Inventory Management Agreement, IMA customers are customers that have agreed to share confidential sales activity with Watson in order to streamline their inventory.)

9. CII Schedule Drugs and SOMS blocks

SOMS – Suspicious Order Monitoring System (Of Control Drugs Substances)
The Master Data Administrator (MDA) will be responsible to ensure that pending sales orders on hold due to suspicious order violations (SOMS) are investigated. The MDA will execute VA05 to determine the value and priority of the orders blocked due to SOMS violations. A MDA will print the SOMS form. The SOMS form contains Class of Trade (COT) averages and customer allowable/order and customer allowable/month.

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The MDA will review the SOMS form to determine if customer contact is necessary. If customer contact is necessary, the MDA will contact the customer. If necessary, the customer contact information can be obtained from the CRA responsible for the account. The MDA will contact the customer to determine if the order should be considered an 'order of interest'. If the customer decides to cancel or reduce the quantity, they will need to provide a reason for the reduction or cancellation. All orders that require additional analysis should be communicated to the appropriate CRA and CRA Manager.

The following procedure is used to identify if the order is at or over the allowance Watson gives the customer which will assist in determining the degree of analysis needed to release the order. Each order is evaluated and the best release code is applied to each order at that time.

Put the number that's in the "Order Quantity" column into the "Release Qty" column. Then, mathematically ADD the following columns "MTD Qty" plus the "Release Qty" to give you a total order quantity to date.

- The 'Pending Qty' column on the SOMS form shows other orders (not the one currently being viewed) that are on SOMS block for the same customer and product. This is to make the MDA aware of other order quantities in the system. The MDA should take the 'Pending Qty' into consideration when completing the analysis of the current order (the one being viewed).

- When releasing the order the MDA will use the most appropriate reason code for each order.

- If the "MTD Qty" plus the" Release Qty" is equal to or less than the "Customer allow/mth", then customer contact is not required.

- If the "MTD Qty" plus the "Release Qty" is greater than the "Customer Allow/mth", then further analysis is need and SOMS form will need 2nd signature from management.
  Some of the tools used during analysis:
    - Current month call log.
    - 852 & 867 data if available.
    - Past shipping history; Year over Year (YOY) or Year to Date (YTD) comparison.
    - Contact internal departments (i.e. Marketing, Demand Management, and CRA) to verify if they had information to assist in the analysis (i.e. Updated forecast, special orders. short-date, etc...).
    - Customer contact.

  o When contacting the customer via email, the following verbiage should be used.
  o Subject: *"Company Name" Order(s) on Hold*
  o Body of email:
    - *Hi (Addressee(s)), in accordance with 21 CFR 1301.74, we are required to conduct independent analysis of orders prior to completing a sale to determine whether substances are likely to be diverted from legitimate channels. You have been contacted due to the fact that your order placed today has prompted further analysis based on a deviation in one of the following areas; unusual size, frequency, or pattern. In an effort to expedite the investigation process and mitigate any delays or inconvenience, we are requesting supporting information necessary to justify the fulfillment of the order in question.*

    - *PO#*
    - *NDC#, Mat#, QTY*

    - *Please note the entire order is on hold. Your quick response will ensure your entire order will be released in a timely manner.*

    Salutation

- The 'Release Qty' column on the SOMS form will need to be filled in by the MDA; this is the quantity that the MDA releases. Usually the 'Release Qty' is the same as the 'Order Qty', unless the customer requests to reduce or cancel the order or the MDA determine the quantity should be reduced with Management approval.

- If the customer decides to reduce or cancel the order, the MDA will make the appropriate changes to the order when releasing the SOMS block. The MDA will request a reason for the reduction or cancellation of the order. Also, depending on the cancellation reason the MDA may forward the cancellation request to DEA Affairs for review. Please note: For IMA customers, if an increase is requested by the customer, the customer would need to be referred to the customer's CRA to have that request completed, and the increased order quantity will go through IMA again. (IMA stands for Inventory Management Agreement, IMA customers are customers that have agreed to share confidential sales activity with Watson in order to streamline their inventory.)

- If the customer is contacted, the MDA will attach supporting documentation to the SOMS form which will include the customer contact name, phone number and/or email, reason for the increase, PO#, SD#, and date of order, and the SKU/Material number and description of the product released. If the same SKU/Material suspends again in the same month, the MDA will determine if the original resolution is appropriate for subsequent orders or if further analysis is needed.

- If the customer decides to reduce the order quantity, the order may come off of SOMS violation hold automatically once the change has been made. If the order appears on the VA05 list after the change, then the MDA will need to evaluate the SOMS form again per standard procedures. Also if the customer decides to cancel the order, then the order may come off of SOMS violation. The MDA will need to execute the VA05 again to verify the order is not on the VA05 list.

- The MDA group should make an effort to get to know the customers and their customers. With that said, if the customer's response is a general response, i.e. increase due to new customers: it is recommended the MDA try to obtain the name, city, & state in which the new customer is located. Please know, the customer has the right to deny this request.

Once this SOMS form is confirmed and verified, the MDA will release the SOMS violation block.
Otherwise, the MDA will escalate the 'order of interest' (SOMS) to the DEA Affairs department for review and feedback. If DEA Affairs determines the 'order of interest' (SOMS) needs to be communicated to the DEA. Then DEA Affairs will contact the DEA.

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B. Filing: Record Retention:

- Class 2 and 2N's are filed in a separate filing cabinet. The DEA requires all Class 2 and 2N's to be filed separately from the 3, 3N, 4 and 5. All SOMS are filed by the account name, account number, City and State, by most current date. If within the same day there are multiple SOMS, then the most current Sales Document number is filed on top.

  Also, there are four states Kansas, Kentucky, New York and Rhode Island which DO NOT allow CONTROLLED samples sent to ANY practitioners.

NOTE: If the customer requests to cancel the order or reduce a line quantity of a Class II (CII) order, an email of the change must be sent to Dept. Coordinator II in Gurnee.

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C. License for One Time Customer:

The Master Data group will create a one-time Master Data template (shell) only once, as necessary. This shell will be used to create orders for one-time customers. A one-time customer shell will be used by order processing to create orders for situations where a permanent Master Data record is not needed, such as Tradeshows or Replacement Orders. **A One-time customer shell SHOULD NEVER be used for any site order or control substance order. A Customer Master account must be set up in order to place these order types.** These templates do not include entry of financial (company-level) data; as such, its usage should be restricted to free of charge orders (i.e., samples, literature etc.). If the one-time customer shell is used to generate a sales order, this record will supply basic customer master information and requires the order processing user to input key fields (i.e., name, address etc). The Master Data group will create the appropriate license for a one-time customer and link the license to the one-time ship-to customer's sales order.

D. Unlicensed Locations:

If a representative receives an order for prescription drugs for an unlicensed location, he/she must obtain the license of an individual who will accept responsibility for drugs being shipped to that specific location.
Such customers may include:
- Dialysis Centers
- Universities
- Health Organizations
- Clinics
- Humanitarian Aid
- Family Planning/Planned Parenthood

The account will then have the Facility's name in name 1 and the responsible doctor's name in name 2, the facility's address. The responsible doctor's state license will be attached at the account level.

In the event the request is submitted with a Mid-Level Practitioner's license, the Master Data Administrator (MDA) will verify that the Mid-Level practitioner is able to receive product by reviewing the Buzzeo PDMA quarterly spreadsheet by logging into the Dendrite website, State Monitor section. The Mid-Level Practioner's name will then be on name 2 of the account.

On occasion an order will come in for an unlicensed Watson facility. When the order comes in it will go to License Block (VE31). In order to release this order from license block, a mock license will need to be created; the license will only be valid for one business day. Once the order has shipped the license will be expired. Only a State License with a the single schedule of RX (no controls) will be created, the license number will typically be the first six characters of the city of the unlicensed facility or enough characters to be able to distinguish the location. For example if the order was going to Parsippany, NJ the license number would be PARSIP. The license will be attached at the account/Master Data level. If the order is for a TRADESHOW a mock license will be created as stated above except the license number will be "TRADESHOW".

On occasion we will receive an order from the FDA for Samples which the FDA does not have a State Board of Pharmacy license. If this is the case, you will need to create a 1 day State license with the external license number with the word FDA followed by the 10 digit telephone number (i.e. "FDA3123535863"). Expire the license once the DD# has been created.

E. Methamphetamine Control Act:

The Master Data Administrator (MDA) will create a valid DEA or State license for any Meth Act products. The DEA license is preferred; if DEA is not available the State license will be used. The system will display the DEA or State license on the packing slip for all Watson products; this is done to be in compliance with State regulations.

F. Indigent Accounts:

Quarterlies (As of 4/2007, DaVita Healthcare is the only customer of this sort)
> These customers place orders on a quarterly basis and the account should be created in the clinic's name. These clinics usually do not have a license of their own so the account will then have the Facility's name in name 1 and the responsible doctor's name in name 2, the facility's address and the responsible doctor's state license attached at the account level. In the unlikely event that a clinic has its own license, the account will be created in the clinic's name and the clinic's license will be linked at the customer master level.

Dailies
> These customers place orders on a daily basis and the account should be created in the physician's name, even if his office is located in a hospital or clinic. If the physician wants to ship goods to numerous locations, a Sold-To should be created for the primary location and Ship-To's should be created for the additional locations. All accounts are to be linked to the same state license even if the address does not match the license as long as this does not violate PDMA regulations. Note: The Sold-To address is usually the address that is on the physician's state license, but the physician may choose not to ship goods to the address listed on the state license, in this case the physician will choose another address as the Sold-To. If, at a later time, the physician wants to ship goods to the address listed on the state license, that account may be created as a Ship-To and linked to the existing Sold-To.

Trelstar and Indigents
> Trelstar and Indigent orders are top priority and should be released as soon as possible following standard procedures.

G. PapSure Physician Address Changes:

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NOTE: You do not need a license for PapSure orders, since the Material master record considers PapSure as an OTC product, therefore, the order should not be held up for a license.

H. R&D Research and Development:

This section may pertain to Clinical Research, Calibration and Marketing Demonstration Requests. In-house shipments for prescription items to facilities for research and/or development purposes do not require licensing. Please refer to "Unlicensed Locations" section for in-house shipments. Shipments going to outside companies require a valid State or DEA license. **Exhibit A - NTIS National Technical Information Services**

ALLERGAN_MDL_01175584

A   Watson Pharma, Inc.

Call Center Operations
Master Data / License Admin. Operational Procedure

PROCEDURE:	Create, Change or Create Listing/Exclusion for Controlled and Non-Controlled substance License		
Revision Number:	GUROPDLAR 507001.003	Effective Date:	May 5, 2004
Revision Written By:	Larry Shaffer Mary Moskello Victoria Lepore	Revision Date:	January 5, 2012
			Page 12 of 12

Exhibit A – NTIS continued…

DEA Number	Exp. Date	Company Name	State	Zip
AC0393734	8/31/2005	CITY PHARMACY INC	TN	37745
AT7665627	11/30/2005	SUSONG PHARMACY	TN	37745
BS0143850	2/28/2007	STUMM, HARRY J MD	TN	37745
BP0093247	3/31/2007	PATTERSON, MARK DAVID MD	TN	37745
MM0369365	1/31/2008	MCMILLIAN, JEFFREY OD	TN	37745
MR0852081	4/30/2005	ROBBINS, MELISSA A FNP	TN	37745
MM0467426	1/31/2006	MORRISON, REBECCA A PNP	TN	37745
MP0551011	3/31/2006	PACE, NANCY L NP	TN	37745
MC0649472	8/31/2006	CARRINO, THOMAS PA	TN	37745
BW8300220	5/31/2004	WALGREEN CO	TN	37745
BT4966288	11/30/2004	THE MEDICINE SHOPPE	TN	37745
AC0431202	12/31/2004	REVCO DISCOUNT DRUG CTRS, INC	TN	37745
AR8276405	12/31/2004	REVCO DISCOUNT DRUG CTRS. INC	TN	37745
DF0029589	9/30/2005	FOOD CITY PHARMACY #606	TN	37745
BH2484032	10/31/2005	HOWARD'S PHARMACY	TN	37745
BR3339618	6/30/2006	RITE AID OF TENNESSEE INC	TN	37745
BG8618689	9/30/2006	GREENE COUNTY DRUG STORE, LLC	TN	37745

Select the hyperlink that matches the DEA information searching for.

ini.net

NTIS
National Technical Information Service

Current Date: 3/15/2004   Data File Release Date: March 11, 2004

Drug Enforcement Administration (DEA) Datafiles –Both

Registrant Profile

for

CITY PHARMACY INC

Address:	113 E CHURCH ST GREENEVILLE, TN 37745
State / Zip:	TN 37745
DEA Number:	AC0393734
Business Activity Code:	A
Drug Schedule:	22N 33N 4 5
Expiration Date:	8/31/2005

[Print] [Close]

Standard Abbreviations			
CRA	Customer Relations Administrator		
DEA	Drug Enforcement Administration		
MDA	Master Data Administrator		
MTD	Month to Date		
NTIS	National Technical Information Service		
PDMA	Prescription Drug Marketing Act		
SOMS	Suspicious Order Monitoring System (of Control Drugs Substances)		
YOY	Year Over Year		
YTD	Year To Date		

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ALLERGAN_MDL_01175585

Actavis Inc.

12

Message

From:	Nancy Baran [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=NBARAN]
Sent:	8/18/2009 10:55:26 PM
To:	John LaRocca [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=JLAROCCA]
CC:	Michael Perfetto [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=MPERFETTO]; Doug Boothe [/O=ONETEAM/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=DBOOTHE]
Subject:	FW: Suspicious Orders

John,

The quick answer to the first part of your question is that we do have a process in place to govern the ordering of controlled drugs. The longer answer is that I believe our process is not current and there is significant room for improvement. I have recommended that we bring in a few key players from different functional areas all of whom have shared ownership in the process. The main goal is to confirm that we are meeting our obligation as a manufacturer of these controlled drugs. This task is on our project list. I plan on leading the initiative and IT has committed to providing development support as needed.

The process as it stands today dates back to November of 2000 when the Suspicious Order Report was developed. As far as I can tell, there have been little or no changes to the report since that time. A brief explanation of how the report was intended to work is as follows -

An order appears on the suspicious order report if it meets the following criteria:

- If the amount ordered by the customer is 25% over the customer's rolling average (**see e-mail below for more details**)
- The 25% threshold will increase to 40% for abuse type drugs.
- The suspicious order report is printed several times/day. There is a separate suspicious order report for SSL and SOD.
- The report is printed automatically at the time that the EDI orders are received. The report does not include manually entered orders.
- Customer Service reviews (eyeballs) the suspicious order report throughout the day (when a new report is created).
- Any order that looks unusual is investigated and any unusual items are cleared before the order is released.

Hamlin, Lisa

From:	Hamlin, Lisa
Sent:	Friday, November 03, 2000 12:05 PM
To:	Levitt, Michael
Cc:	Corridon, Pat; Reed, John
Subject:	Suspicious Order Report

Suspicious Order Report:

At the beginning of each month, the program looks back over last month's **invoices** by customer and item

All the quantities **ordered** and a count of the number of lines are totaled and saved.

The totals of each for the past 6 months (rolling) are added up and an average is computed by dividing the 6 month qty ord / 6 month line count.

This is your "customer item average".

New sales orders are considered suspicious if the qty ordered is more than 1.25 * the customer average (ie., more than 25% over average).
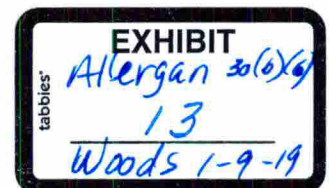
EXHIBIT
Allergan 30(6)(g)
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Woods 1-9-19

ALLERGAN_MDL_02081243

Examples:
if you order 1,000 once a month, your average is 1,000
if you order 10 times a month, 100 units each time, your average is 100.

Lisa R. Hamlin
Information Services Manager
Faulding Inc
Tel: (908) 659-2394 / Fax: (908) 659-2545
mailto:lisa.hamlin@us.faulding.com
http://www.faulding.com

To answer the second part of your question —

We would never ship to unfamiliar customers. Our system is set up to prevent shipping a controlled product to a customer without a valid DEA license.....which is a document governed by the DEA who determines the customers eligibility. Our customer master database is updated monthly by means of a download of their eligibility data. Without a valid DEA license, an order will fail at point of entry. Our system (MFG PRO) will generate a failure report for any order rejected for DEA purposes/lack of current license in our system. Our 3rd party logistic provider (UPS-SCS) has a level of security equally as secure as our systems acting as a secondary ckeckpoint. This makes it virtually impossible to sell to a customer that is not authorized to distribute controlled products.

I hope that I have sufficiently answered your questions and apologize if I have provided more detail than you were looking for. If you have any further questions, don't hesitate to ask.

Nancy

Nancy Baran
Senior Manager, Customer Service

actavis
creating value in pharmaceuticals

Actavis
60 Columbia Rd. Bldg B ℓ 973-993-4510 @ NBARAN@actavis.com
Morristown , NJ 07960 United States   w www.actavis.com
Internal VoIP number ℓ 1254510

From: John LaRocca
Sent: Friday, August 14, 2009 6:58 PM
To: Nancy Baran; Michael Perfetto
Cc: Doug Boothe
Subject: Suspicious Orders

Nancy, Mike – do we have a written procedure in place to govern the handling of orders for Class II drugs that are out of line with previous experience from customers, from unknown customers, or are for unprecedented amounts? Also what is the procedure by which we get comfortable that our customers are registered and permitted to handle Class II's?

John LaRocca
Vice President/Chief Legal Officer

actavis
creating value in pharmaceuticals

Actavis
60 Columbia Rd. Bldg B   ℡ +1 973-889-6602 @ JLAROCCA@actavis.com
Morristown , NJ 07960 United States ℻ 1 973-993-4306 w www.actavis.com
Internal VoIP number ℡ 1256602

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<u>Suspicious Order Report:</u>

At the beginning of each month, the program looks back over last month's **invoices** for regular sales transaction(Memo items are skipped).

All the quantities **ordered** and a count of the number of lines are totaled and saved on **MONTHLY** basis by **customer / part** combination.

Overall, system stores the LAST 6 months of data(Ordered Qty , Total Lines) . The totals of each for the past 6 months (rolling) are added up and an average is computed by dividing the 6 month qty ord / 6 month line count.

This is your "customer item average".

New sales orders are considered suspicious if the qty ordered is more than **1.25** * the customer average (ie., more than 25% over average).

Examples:
if you order 1,000 once a month, your average is 1,000
if you order 10 times a month, 100 units each time, your average is 100.

Note : If no average data exists for the customer/part combination, "First time purchase" info is displayed on the report.

The program also has provision where the variable %age can be setup in the generalized code master for different items.

If the item exceeds the **variable setup percentage**, the sales order is put ON HOLD by assigning the action status field of sales order as **"CS".**

EXHIBIT
Allergan 30(6)(6)
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Woods 1-9-19

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Suspicious Order Report for Oxycodone IR Tablets
Standard Operating Procedure
Commercial

Action	Responsibility
1. **Monitor Monthly Customer Orders**. Run a Monthly tracking report at a minimum of once per month in the Actavis order reporting system, for Oxycodone IR Tablets. Export the file into Excel and store on the shared Marketing file for Oxycodone IR Suspicious Order tracking.	Marketing – Product Manager
a. Compare the month – to – date orders for each customer, down to the customer DC level, against the rolling six month order history. Identify any individual customer locations that have ordered 50% or greater than their established six month order average. These customer's will be noted in the Suspicious Order Tracking Form – see attachment A	Product Manager
b. Forward the Suspicious Customer Order Tracking Form to the VP of Sales and individual sales team account representative, with details of order history and current month to date order status.	Product Manager
c. Contact customer service and have the open orders for the specific account placed on "HOLD" status until the inquiry is completed and resolved. Customer service may alert the specific customer that the open orders are placed on hold due to inquiry of order tracking.	
2. **Customer Inquiry**. Contact each customer, within a target timeframe of 3 business days, who is on the monthly Suspicious Order Tracking form, either by email, in person, or phone, regarding the higher volume orders. Note reasons for the order volume and duration that the orders will be increased	VP of Sales Team
3. **Documentation of Follow-Up**	
a. Forward all details of customer communication to the Marketing Product Manager via email, within a one week time frame.	VP of Sales / Sales Team
b. Fill in Suspicious Order Tracking Form (Attachment A) with details of customer communication.	
c. Send file back to the Marketing Product Manager. This file will be stored on the Marketing shared drive.	
4. **Decision Regarding Future Customer Shipments**	
a. Based on feedback from the customer, make a determination whether to continue shipping the customer. The following criteria may be applied to help with the decision: new customer (still establishing 6 month history), market growth, market shortage, expansion of customer business (adding new stores, channels)	Marketing/ Customer Service Sales team
b. If the decision has been made to not ship the customer's open orders, notify customer service to have the orders/account placed on suspended status.	Marketing – Product Manager
c. Notify appropriate personnel with the details of the orders and order history. Keep the open orders and any new orders that come in on the customer location on Hold status until clearance is given to resume shipping the customer	Marketing/Customer Service

Oxycodone IR Tablets
Suspicious Order Tracking
Customer:

Date	Strength	6 month Order Average	Current Month Order	Actavis Sales Team Member	Date	Customer Contact Procedure			Actavis Decision
						Form of communication (email, in person, phone)	Customer Name and Position	Reason given for higher volume in orders	

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actavis	**Business Procedure**	**Actavis Group**

Title: ACTAVIS Suspicious Order Monitoring - DIRECT Customer Sales SOP		
Number/Revision:	Effective Date:	Ref. to Corporate Procedure:
Prepared by: Signature:	Date:	Reviewed/Approved by:	Date:
Issued by: Signature:	Date:	Invalidated by: Signature:	Date:

1. PURPOSE

1.1. This procedure describes the process used to identify and report controlled substance suspicious orders to the Drug Enforcement Administration (DEA).

2. SCOPE

2.1. This policy applies to the sale of all Controlled Drugs sold by Actavis (Schedule II-V).
This procedure applies to the direct sales function of Controlled Drugs sold by Actavis.

3. DEFINITIONS

3.1. CONTROLLED DRUGS:

Controlled Drugs are defined as any drug or therapeutic agent-commonly understood to include narcotics, with a potential for abuse or addiction, which is held under strict governmental control, as delineated by the Comprehensive Drug Abuse Prevention & Control Act passed in 1970.

3.2. SUSPICIOUS ORDERS:

These are controlled substance orders which are of unusual size, deviate substantially from a normal pattern or are of unusual frequency.

21 CFR 1301.74(b) states that "the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

3.3. **PEND:** These are orders which have been blocked or stopped in real time because they exceeded the calculations and business rules established by Actavis. "Pended" orders are deemed "questionable" until they are investigated, during which time they are referred to as **"Orders of Interest or "OI"**.

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* Fill in N/A if question is Non Applicable to the Audit
SOM SOP AND BUSINESS PROCEDURE DIRECT

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4.   **RESPONSIBILITY**

4.1.   The company's suspicious order monitoring program begins by participating in a series of due diligence activities to ensure that we "know our customer." Profiles for each of its direct customers assist Actavis in understanding its customers' buying needs and habits. This information is part of the process of identifying controlled substance orders that are suspicious. The significant efforts related to SOM demonstrate Actavis' commitment to protecting the integrity of the supply chain and to preventing the diversion of controlled substances.

4.2.   The role of Ordering Monitoring Business Analyst is the initial line of accountability for identifying and investigating potentially suspicious orders by monitoring sales order data. The Order Monitoring Business Analyst is responsible for monitoring incoming orders for direct sales, outgoing data for suspicious order activity, utilizing electronic systems and following Standard Operating Procedures (SOPs).

4.3.   The role of Order Monitoring Manager is to oversee the data analysis by the Order Monitoring Analysts. This role reviews, approves and escalates, as needed, all sales and distribution data reporting related to suspicious order monitoring activity.

5.   **RELATED DOCUMENTS**

5.1.   Title 21, Code of Federal Regulations, Section 1301.74(b); Letters from the Drug Enforcement Administration dated September 27, 2006, February 7, 2007 and December 27, 2007.

6.   **NEW ACCOUNTS**

6.1   Due diligence is performed on all new accounts by Actavis. The sales organization initiates all requests to open new customers. Prior to the internal "due diligence" process beginning, Sales will provide details that justify the request (ex: sales potential, unmet need, new member of an existing purchasing organization, etc...). Once approved by the Vice President of Sales, a series of due diligence activities will begin. A customer survey/questionnaire is the mechanism used to capture due diligence regarding an account. This information may be completed remotely or in many cases through scheduling an on-site visit. The level of due diligence will vary for customers planning to purchase controlled substances vs. those that do not.

6.2   New accounts intending to purchase controlled drugs will receive a compliance acknowledgment form. By executing this form, the organization represents it is aware of its obligations under federal and state statutes and regulations pertaining to the distribution of controlled substances, including 21 CFR 1301.74(b), and that it has in place measures to ensure compliance with such regulations.

6.2.1   Compliance acknowledgment forms are renewed periodically.

6.3   Approved accounts are entered into an order management database.

    6.3.1   Payment terms are established and approved within the Finance team at Actavis.

    6.3.2   Licensing information is obtained from the customer and maintained within the order management database. Preventative measures are in place to ensure controlled drugs are not shipped to any account without a valid DEA license in place.

7.   PENDED ORDERS

7.1   Actavis customer orders for controlled drugs are individually analyzed via an internal computerized statistical calculation to determine whether the order may be of unusual size, whether the order may deviate substantially from a normal pattern and/or whether the order can be associated with an unusual pattern or frequency. The analysis is accomplished by a formula that uses a statistical algorithm and compares current orders from previous orders. This analysis will assign a "score" to each order based upon the analysis. This score will help to identify the level of suspicion of a pended order. An order will "pend" if any or all of these attributes are present to a statistical extent. These orders may be suspicious and must be investigated before shipping to the customer. Pended orders are referred to as "Orders of Interest."

7.2   Customer orders with no previous history (new customer, new NDC) will "pend" until there are purchases in two distinct months within the last six months. At that point, it becomes part of the mathematical calculations of the model.

8.   CLEARING AN ORDER FROM SUSPICION

8.1   All orders of interest will be "pended" in real time. The entire controlled substance order will "pend" until investigated and either cleared of suspicion or reported to DEA.

8.2   All "pended" orders will then be initially reviewed by the SOM Analyst. The specific order information is presented on a series of reports for purposes of analysis.

8.3   Orders are typically investigated for clearance by the date submitted on a first in, first out basis with some exceptions (ex: new product launches, etc...). Reporting details on the order pending include but are not limited to: order date and time, SO#, Customer #, Customer Name, Customer Family, PO#, Total # of lines and total # of lines considered as OI, pended lines with product and quantity along with possible reason codes that best categorize why the order is being considered an Order of Interest.

8.4   The SOM Analyst will gather relevant information to begin the review process. The following information will initially be considered:

    A.   The customer's order history with this drug. (ex: may be a new award, new product launch, etc...). A review of anticipated purchases may be necessary to aid in the investigation.

B. Any "notes" in the customer file pertaining to the drug that has been "pended."

C. Whether other orders for this account have been "pended" before and what actions were taken on these pended orders.

8.5 After organizing this information, the SOM Analyst will first attempt a full internal investigation to determine why the order may be pending (ex: new launch, new award, product issue in the market causing increased demand, etc...). In the event an internal investigation is unable to provide adequate information to clear the pended order, the customer may be contacted. The SOM Analyst will advise the customer in general terms of why the order pended (i.e., appeared to be larger than what was frequently ordered, appeared to be more frequent or appeared to be indicative of a trend). Questions should be "open-ended" and customer accounts should not be "guided" to provide the "right" answer. All investigation results are fully documented within the order management system. Complete audit trails will exist for all documentation and releases.

8.6 Some of the types of reasons that might allow the staff to clear and order of suspicion include:

- Order error
- Purchasing Incentives/Promotions
- New customer or new product award
- Verified increased market growth (ex: new study)
- Market conditions (ex: market shortages related to raw materials, market shortage related to a change in the # of suppliers, recalls, shift in purchases from one customer location to another (ex: change in warehousing strategies).
- New or different drug
- Different size or preparation
- Seasonality

8.7 If the order cannot be cleared or if customer has had previous orders pended and provided similar reasons, the reasons will be further investigated. The SOM Analyst will consult with the Order Monitoring Manager.

8.8 In the event the Order Monitoring Manager is unable to justify the release of the pended order through additional investigation, Actavis DEA Affairs team and/or Customer Service Management may jointly participate in partnership calls with the customer to gather additional information.

8.9 Once sufficient information is obtained, the order will be released from hold.

9. REPORTING A SUSPICIOUS ORDER TO THE DEA

9.1 If an order cannot be cleared of suspicion, Actavis DEA Affairs will alert the local office of the DEA by phone of the suspicious order activity.

9.2 The order will be cancelled in its entirety and the account will be re-examined for possible closure.

9.3   Any conversations with any DEA employee will be documented to include both the Actavis and DEA participants, date of contact, customer and product order details along with a summary of the conversation and descriptions of actions to be taken.

9.4   After the DEA has been contacted by phone, a written notification will follow for all suspicious orders. All relevant information will be forwarded to the DEA, both at headquarters and the field office with jurisdiction for the customer who is ordering the controlled substances.

10.   EXISTING CUSTOMER DUE DILIGENCE

10.1   Initial and follow-up site visits will be scheduled for accounts on a risk-adjusted basis.

10.2   The purpose of customer site visits is to conduct a high-level "due diligence" review of their SOM program, in an attempt to assure they are exercising regulatory controls and procedures relating to the further sale of Actavis' Controlled substances in a manner consistent with the Drug Enforcement Agency (DEA) regulations and published procedures.

10.3   A customer questionnaire/site survey form is used to document due diligence compiled either remotely or at a customer's site. The contents of a standard survey may be utilized differently based upon the type of customer being surveyed (ex: corporate headquarters vs. distribution center).

11.   INTERNAL AUDIT PROGRAM

11.1   All pended orders will have a complete audit trail within the order management system.

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* Fill in N/A if question is Non Applicable to the Audit   Page 5 of 5
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![actavis]	**Business Procedure**	*Actavis Group*

Title:	ACTAVIS Suspicious Order Monitoring - Indirect Customer Sales SOP	
Number/Revision:	Effective Date:	Ref. to Corporate Procedure:
Prepared by: Signature:	Date:	Reviewed/Approved by:	Date:
Issued by: Signature:	Date:	Invalidated by: Signature:	Date:

1. PURPOSE

1.1 This procedure describes the process used to analyze and monitor customer purchases from wholesalers and distributors

2. SCOPE

2.1 This policy applies to the indirect sale of Controlled Drugs sold by Actavis (Schedule II-V), identified as "products of interest" by the SOM Steering Committee.

2.2 This procedure applies to the indirect sales function of Controlled Drugs sold by Actavis.

3. DEFINITIONS

3.1 **CONTROLLED DRUGS:**

Controlled Drugs are defined as any drug or therapeutic agent-commonly   understood to include narcotics, with a potential for abuse or addiction, which is held under strict governmental control, as delineated by the Comprehensive Drug Abuse Prevention & Control Act passed in 1970.

3.2 **SUSPICIOUS ORDERS:**

These are controlled substance orders which are of unusual size, deviate substantially from a normal pattern or are of unusual frequency.

21 CFR 1301.74(b) states that "the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

3.3 **INDIRECT CUSTOMER:**

This is a customer who does not purchase products directly from the Actavis warehouse. An indirect customer purchases product from a wholesaler or distributor.

EXHIBIT
Allergan 3d(b)(6)
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Woods 1-9-19

ALLERGAN_MDL_01979834

Actavis will commit to monitoring indirect customers who purchase an average quantity of 50,000 units of a CII controlled substance on a yearly basis.

3.4 **PRODUCTS OF INTEREST:** This is an Actavis product that is identified and agreed upon by the SOM Steering Committee, to be at higher risk for abuse and diversion and should be monitored by additional measures. An identified product of interest will be subject to Suspicious Order Monitoring - Indirect Customer Sales SOP. A product of interest can be declassified as a "product of interest" by the SOM Steering Committee, per intelligence and research & also through contact with the DEA. This will be revised, updating or removing products, as needed.

3.5 **Q4biz:** This is an Actavis sales and shipping inventory computer system.

4. RESPONSIBILITY

4.1 The role of Ordering Monitoring Business Analyst is the initial line of accountability for monitoring indirect sales utilizing ValuCentric and EDI data at an aggregate level for suspicious activity. The Order Monitoring Business Analyst is responsible for utilizing electronic systems and following Standard Operating Procedures (SOPs).

4.2 The role of Order Monitoring Manager is to oversee the data analysis by the Order Monitoring Analysts. This role reviews, approves and escalates, as needed, all sales and distribution data reporting related to suspicious order monitoring activity of indirect customers.

5. RELATED DOCUMENTS

5.1 Title 21, Code of Federal Regulations, Section 1301.74(b); Letters from the Drug Enforcement Administration dated September 27, 2006, February 7, 2007 and December 27, 2007.

6. IDENTIFICATION OF CUSTOMER POOL

6.1 A quarterly analysis of direct customers buying CII narcotics will be performed to identify the direct wholesalers and distributors that will be monitored for this SOP. Any direct wholesaler or distributor that purchases a quantity of 50,000 units or greater on an annual basis of CII narcotics will need to be monitored per this SOP for their indirect customer purchases. The quarterly analysis will be performed using Q4biz or a comparable program. The quantity of 50,000 units of a CII substance can be changed either in quantity or product makeup by the SOM steering committee or a designated body.

7. INDIRECT CUSTOMERS BUYING FROM MULTIPLE SOURCES

7.1 Monthly analysis should be performed by using the Valuetrack "Safe and Secure" Module, or a comparable program, to monitor for pharmacies or other individual stores buying Actavis controlled substances of the same product from more than one wholesaler or distributor during a two-week period.

Fill in N/A if question is Non Applicable to the Audit   Page 3 of 5

SOM SOP AND BUSINESS PROCEDURE INDIRECT

7.2. If high activity is observed of a single store/pharmacy buying the same product from three or more sources (wholesalers/distributors) during the two-week time period, Actavis will then contact the point of sale wholesalers or distributors to alert them to this activity. Depending on the frequency and purchase quantity of the indirect customer, Actavis can initiate actions to prevent the indirect customer from receiving product.

7.3 Actavis will keep records of the notification from Actavis to the point of sale customer. Records will be kept of any follow up information, actions, and results. If the results include a change in customer forecasts, that will be noted and handled by the Marketing/Product Management Department.

8. INDIRECT CUSTOMERS BUYING HIGH QUANTITIES OF CONTROLLED PRODUCTS.

8.1 Actavis indirect customer sales will be monitored through Valuetrack "Safe and Secure" module, or a comparable program, on a monthly basis. The sales will be monitored for higher than average purchases of a single product based on the previous 3 months of purchases.

8.2 If a pharmacy or individual store's previous 30- day purchases exceed 50% higher than their established 3 month average, notification will be sent by Actavis to the point of sale wholesaler or distributor highlighting the current order quantity and historical average. Actavis will request documentation of the reason behind the increase. If no reason or response is given, then Actavis will follow up with the point of sale wholesaler or distributor again as needed.

8.3 Actavis will keep records of the notification from Actavis to the point of sale customer. Records will be kept of any follow up information, actions, and results. If the results include a change in customer forecasts, that will be noted and handled by the Marketing/Product Management Department.

9. INDIRECT CUSTOMERS BUYING DISPROPORTIONATE AMOUNT OF CONTROLLED SUBSTANCES

9.1 Actavis indirect customer sales will be monitored through Valuetrack "Safe and Secure" module, or a comparable program, on a monthly basis. The sales will be monitored for disproportionate amounts of controlled substances purchased from a single pharmacy or end user store, compared to their historical purchases or what is expected/forecasted from the end user store. Certain stores may have a higher expected utilization of controlled substances due to their internal warehousing strategy.

9.2 If any substantial change in product mix purchases is observed (with a higher amount of controlled substance purchased), Actavis will then send a notification to the point of sale wholesaler or distributer with the current product mix and how that has changed from their prior utilization. Actavis will request documentation of the reason behind the increase. If no reason or response is given, then Actavis will follow up with the point of sale wholesaler or distributor again in approximately 14 days time.

9.3 Actavis will keep records of the notification from Actavis to the point of sale customer. Records will be kept of any follow up information, actions, and results. If

Fill in N/A if question is Non Applicable to the Audit   Page 4 of 5
SOM SOP AND BUSINESS PROCEDURE INDIRECT

the results include a change in customer forecasts, that will be noted and handled by the Marketing/Product Management Department.

10. MEETINGS WITH HIGH VOLUME WHOLESALERS

10.1 Actavis will hold periodic partnership meetings with the top volume wholesalers who sell to individual stores and pharmacies to discuss retailers/customers of interest. Participating in this meeting could be representatives from one or more of the Actavis functional areas: Sales and Marketing, Customer Service, Legal, and Compliance.

10.2 During the meetings any outstanding notices of indirect customers buying from multiple sources, higher than normal quantities, or disproportionate activity will be discussed. Actavis will take any items that have not been addressed to the team's satisfaction to the Actavis SOM Steering Committee for further action.

11. REPORTING SUSPICIOUS ACTIVITY TO THE DEA

11.1 Depending on the frequency and severity of the indirect individual customer ordering, Actavis can reserve the right to stop sending the product of interest to the point of sale wholesaler, and will notify the DEA to the suspicious activity of the indirect customer, and the point of sale wholesaler. Notification to the DEA will be performed and recorded using the DEA Telephone Contact Report as a record and procedure for this activity.

12. REPORTING SUSPICIOUS ACTIVITY TO THE DEA

12.1 All documentation regarding the analysis and findings will be kept and maintained in a global access database such as SharePoint, or a comparable system.

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US Order Management
Master Data / License Admin. Operational Procedure

PROCEDURE:	License Maintenance Create, Change License or Create, Change Listing/Exclusion for Controlled and Non-Controlled substance License		
USOM POLICY #:	USOM-LIC-4000	Effective Date	May 3, 2004
Revision written by:	Victoria Lepore Mary Moskello	Revision date:	June 5, 2014
USOM CTMAN Document #	CTMAN 080-045		
CTM Transaction:	VX01N- License Create VX02N- License Change VB01- Create Listing / Exclusion VB02- Change Listing / Exclusion VE30- Existing Licenses VE31- License Blocked Sales Orders VCII1- Create Batch Search Strategy VCII2- Change Batch Search Strategy		
Prerequisites SAP Transaction Code	VD01- Create Customer VD02- Change Customer		
Post réquisits SAP Transaction Code			

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Purpose

Establish and maintain the proper method of applying licensing information on an account to ensure compliance with the Drug Enforcement Administration (DEA) licensing requirements and the Prescription Drug Marketing Act (PDMA), as well as, the National Association of Boards of Pharmacy.

Scope

All Call Center Operations employees directly or indirectly responsible for customer account maintenance
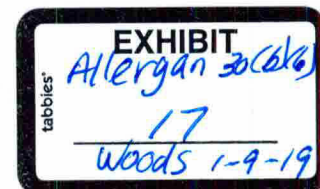
Procedure

Once a customer account has been opened, updated, or unblocked, the Master Data Administrator (MDA) will review and verify the licensing information for accuracy.

All information necessary for analysis, review and validation of a license must be submitted to the SAP Master Data Administrator (MDA).

The following information is verified against the current License for accuracy:

1. Customer Name

2. Ship-To Address

Note: Ship-to address MUST match the DEA License. However PDMA regulations policy to ship non-controlled sample products only to a facility that the requesting practitioner operates from. If the address of the licensed

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practitioner does not match the address of the practitioner's license, then the MDA and/or CRA/SAA must verify that the practitioner does practice at the Ship-to address. Verification of the practitioner address may be done by obtaining a copy of the doctor's valid state license, a phone call to the facility, finding the location on the internet via the yellow pages or comparable search engine, or avoided Rx that shows the practitioner at the Ship-to.

3. DEA number / State License

4. DEA expiration date / State License expiration date

5. Approved Drug Schedule(s)

6. It is mandatory that a State license be created on all RX including Florida accounts. Due to the State of Florida Pedigree requirements, it is mandatory that the FL DOH Permit # (State License) appears on all packing list and must be submitted to open a new account.

7. It is important that the State license is NOT expired or else it will not appear on the packing list.

The system is set to capture legal blocks on Florida accounts missing a State license.   There are three scenarios for legal blocks for the State of Florida:

- State legal block during order processing if the ship-to license is missing.
- State legal block during order processing if the ship-to license has expired.
- State legal block during order processing if the ship-to license expires within 7 day ship window.

- There is a SAP Prerequisite requirement that is maintain by IT which is called ZGLOBAL_PARAM table. If another State needs to be added for Epedigree requirements, the MDA will send an email to the IT team to add a State to the ZGLOBAL_PARAM table.

Please take note: Accounts are not deleted or de-activated. When an account is no longer in use, i.e. per customer request, location has moved, or any other reasons, the MDA will block the account and expire all current licenses attached to the account. Also the MDA will report to the Board of Pharmacy, FDA and DEA in 3 business days if unable to authenticate the vendor/customer.

A. DRUG SUBSTANCES – Controlled:

1. DEA License

DEA license is required for orders containing controlled substances. The DEA license includes the DEA license number, DEA license expiration date and the approved drug schedules (2, 2N, 3, 3N, 4, 5).

Schedule	Regulatory Definitions
2	High Potential for abuse. Use may lead to severe physical or psychological dependence. No renewals are permitted
2N	*Same as above except, Non-narcotic*
3	Some potential for abuse. Use may lead to low to moderate physical dependence or high psychological dependence. Up to 5 renewals are allowed within 6 months.
3N	*Same as above except, Non-narcotic*
4	Low potential for abuse. Use may lead to limited dependence either physically or psychologically. Up to 5 renewals are permitted within 6 months.
5	Subject to state and local regulation. Abuse potential is low; a prescription may not be required.
Rx	Prescription *(SAP requirement)*

Verification of the DEA license number, DEA shipping address, and DEA expiration date and drug schedule can be made by:

a. Using The U.S. Department of Commerce National Technical Information Services (NTIS) Drug Enforcement Administration (DEA) website: http://deanumber.com/ (See Exhibit A).

b. Obtaining a photocopy of the DEA license certificate from the customer.

If the copy received from the customer is not legible and does not exist on the DEA website (NTIS) or the DEA license has expired, the MDA will leave the order on license block in SAP, until the appropriate documentation is received. The MDA will contact the customer or the CRA responsible for the account to request a valid/current photocopy of the DEA License. The MDA will update the account upon receipt of a valid DEA license to remove the block on the order in SAP. The MDA will also communicate and report back to the Customer Support department on the licensing status, if necessary.

If the photocopy of the DEA License is not received, the MDA will contact the customer or the CRA responsible for the account a second time requesting the photocopy of the DEA license. If the photocopy of the DEA license is not received, the customer will be notified that the pending order will be cancelled until a valid DEA license is received. The MDA will update the account with an overall block until a valid license has been received. Once a valid license has been received the overall block will be removed.

*NOTE: Only the schedules (2, 2N, 3, 3N, 4, 5) that are registered and shown on the license will be created in SAP. Also, customers with a DEA license automatically receive schedule Rx.

Retail Outlets and Practitioners must register all schedules to receive shipment.

The check digit algorithm will determine the validity of a DEA number. The seventh digit of the DEA number is the Check Digit. Add the first, third, and fifth digits to equal SUM1. Add the second, fourth, and sixth digits and then multiply by 2 for Sum2. Add SUM1 + SUM2. The last digit of this

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total should equal the seventh (Check Digit) of the DEA #.

Note: On occasion DEA licenses with only 1 letter at the beginning (i.e. R10184159) may be submitted. These licenses are usually submitted by customers that have a name that starts with a number (i.e. 212 Pharmacy). The check digit algorithm can still be used by treating the first number as the 2nd letter of a typical DEA license. If necessary, the DEA can be called directly to verify the validity of a license.

DEA check digit algorithm								
For example: DEA License RW0184159								
DEA	First	Second	Third	Fourth	Fifth	Sixth	Seventh (check digit)	Results
RW	0	8		1		9		9	Sum1
		1		4		5		10 x 2 = 20	Sum2

2. Creating Exclusion Record

Three exclusion methods are currently being used, Customer/Schedule Number, SalesDocType/Ord.reason/Sch No., and Customer/Material. The Customer/Schedule Number exclusion is set up is when the customer requests to exclude schedules. The customer may request to exclude schedules because the facility does not have proper storage and/or when the customer does not wish to receive those schedules. The SalesDocType/Ord.reason/Sch No. is setup when it is decided that a specific Order Type (i.e. Standard Order) and Order Reason (i.e. Drop ship) should not receive certain schedules. The Customer/Material is used the when specific materials will not be ordered/shipped to a specific customer.

When the customer is being investigated as directed from management, you need to expire the DEA license and exclude the customer's schedules on 2, 2n, 3, 3n, 4 and 5 and create a State license for that customer.

No **DEA** license is added to any Ship-to unless the Sold-to and Ship-to account included in the request have been vetted and approved by DEA Affairs. All vetting documentation will be maintained by DEA Affairs and applicable approval will be noted on the new account form. Additionally any additional approvals will be noted on the new account form by all appropriate parties prior to the first "ship to" having a DEA license added.

If vetting is not approved, please add internal notes (to include DEA Affairs justification) to the ship to account and exclude all schedules 2, 2n, 3, 3n, 4 and 5 to prevent any orders being processed.
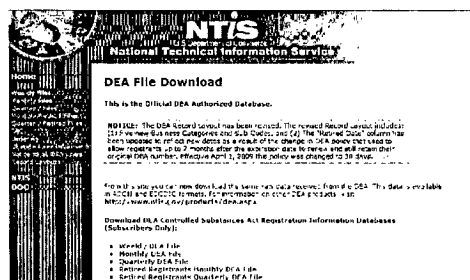
3. Violations

The Master Data Administrator (MDA) will review and release sales orders pending licensing verification. This is critical in order to remain in compliance with the DEA, State and PDMA law as it pertains to the sales and distribution of pharmaceutical products.

4. NTIS Disc

The Master Data Administrator (MDA) will download the NTIS file from the NTIS website on the first business day of the month; Go to www.DEA.NTIS.GOV

The link and the password for the following website will be on the portal
Go to www.DEA.NTIS.GOV
The screen will look as below:

Go to the "monthly file" link either to the left column or the bottom.

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Click on the zipped format link.

Click once on the first file that starts with MA and ends with .zip
This brings up as sign on screen:

The server dea.ntis.gov at DEA Monthly Access requires a
username and password.

User name:

Password:

☐ Remember my password

OK   Cancel

Enter the following information:
Username: 525246
Password: Watson! 2011
Checking the remember password is optional
Click OK

Save file anywhere, usually desktop
Go to the location where you saved it (usually desktop)
Right click on the file and click on extracting all, Click Next
Click OK (the default location is the desktop)
Click Finish
Now open the Customer Master folder and then the sub-folder NTIS File

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- ⊟ 🗀 Customer Master
  - ⊞ 🗀 1 Pending (Initial request)
  - ⊞ 🗀 3 Pending (Accounting)
  - ⊞ 🗀 4 Pending (Contracts)
  - ⊞ 🗀 5 Pending (License)
  - ⊞ 🗀 6 Pending (Notify requestor)
  - ⊞ 🗀 Accounting Completed 2004
  - ⊞ 🗀 CARS Tools
  - ⊞ 🗀 Compensation
  - ⊞ 🗀 Completed
  - ⊞ 🗀 CUSTLISTS
  - ⊞ 🗀 Drive Shortcuts
  - ⊞ 🗀 Licensing Department
  - ⊞ 🗀 MEMBERSHIP
  - ⊞ 🗀 MISC
  - ⊞ 🗀 NTIS File

Click on the location where you stored the recent NTIS file (usually desktop) and drag the file to the NTIS File folder.

Copy the path for this location as below:
V:\Sales Operations & Distribution\Customer Master\NTIS File

Send an email to the IT Dept along with the record count (found on the screen when you clicked on the "Monthly Files" on the original website). Make the subject of the email "NTIS File".

Once the file is loaded into SAP by the IT Dept., an email will be sent to #Master Data on the updated DEA License using downloaded file from NTIS File folder.

*NOTE: On a monthly basis, the DEA registration file information is loaded, by the Information Systems group. The updated information is in accordance with information on file at the DEA. This is inclusive of DEA license expiration date and authorized schedules. However, the DEA registration file information may not be as current as the DEA website mentioned above. The most current data should be used. Please see the Information Systems group update process below:

Monthly DEA License Update from NTIS File Folder Process

1. **Prod Support executes a trial run in a test system** – this is not done to update the license values in the test system, rather to determine whether there are any format or data problems with the CD. In the past 14 months we have had circumstances in which a) dates on the CD were incorrectly formatted and b) schedule values on the CD were not valid (licenses with Schedule 1). It is important to discover these errors and request a replacement CD from NTIS prior to using the CD to update the production system.

2. **Prod Support executes the custom License Update program in the production system** – a brief summary of the functionality of the program:

   Custom Program Name: ZVI_DEA_LICENSE
   Transaction Code: ZVLICUPD

   The program selects all active DEA license records from the SAP system. Each record is then matched against the uploaded NTIS file using DEA number, if found, the end dates and schedules of the SAP license and the NTIS entry are compared. If they are identical, no updates are made in SAP. If they are different (i.e., new end date, different schedules), the existing SAP license is expired and a new license is created using the values from the NTIS entry. If a match is not found, the SAP license is expired, as the validity of the license could not be confirmed with the NTIS file.

   The program also dumps the full content of the NTIS file into a custom SAP table ZVDEA for reference purposes. After completion of the job, the number of records in this table is compared to documentation received with the file to confirm that the record counts match. This is done via transaction code ZVDEA.

   If errors occur during the execution of the job, Prod Support will analyze and correct the errors. The job is usually executed the day the information is available. so that errors can be resolved with limited impact to the business.

3. **Post Processing Reporting** – after processing is complete. Prod Support produces a listing of expired and new licenses, using the SQVI Quick viewer query tool in SAP. The listing shows all licenses expired; and, if a new license was created (in the case of updates). This listing is sent to the Master Data Team for review.

Notes: One issue regarding this process is that a time lag will always potentially exist between receipt/application of the NTIS File and the actual status of the DEA licenses. The Licensing team has access to daily updated information on DEA licenses via the internet, including newly created licenses; they will capture and create/update licenses in the SAP system based on business requirements. However, as noted in the processing summary, if the NTIS File does not contain a license (i.e., perhaps a license just created/approved in the past week, after the latest NTIS File is loaded into the folder), the program will consider it invalid.

The Post Processing listing also contains information about the Created On date and Created by ID of a license. One possibility is for the Master Data Team to review the list by the Created on date, so that expired licenses that were created most recently will be readily apparent. These are the most likely to have been created/updated after the NTIS File was issued, and the Master Data Team can manually update them before any business impact is realized. If the license continues to be missing from the NTIS File month after month (requiring manual re-creation), this should be researched; supposedly, if it's not on the file it doesn't exist.

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Licenses used on specific orders: this is not related to the update process in any way; however, this data is available via standard SAP transaction ENGK, using the Assigned Documents option under Alert Reporting. Among the search criteria available are license type, license number (internal SAP or external/DEA number), and Sold-to customer and schedule number.

5. Licensing Issues

Whenever there is a discrepancy between the information on the licensing website and the account, for example, the customer has recently moved to another address, but the website still reflects the old address. The Customer Relations Administrator should then contact the customer to verify the correct information and obtain the supporting documents. If the account needs to be changed, the CRA/ Specialty Account Administrator will need to fill out the appropriate form and submit according to standard procedures. If the Master Data group cannot update the address on the account within 48 hrs, then the Master Data group should EXPIRE the current license. Once the Master Data group has followed the procedure to correct the address in SAP then validate and re-instate the license according to standard procedures. If the customer has a new license number, then the current license should be expired immediately and a new license should be created according to standard procedures.

Validating Medical Prescriber's State Licenses

The Master Data Administrator will validate the State License using the MEDPRO website.

In the event MEDPRO is not up to date, the Master Data Administrator visits the respective state website. If the MEDPRO and state website reflect an expired license, MDA will notify the CRA/SAA. The CRS/SAA will need to contact the customer to provide an updated license.

6. TIRF REMS Registration

The goals of the TIRF REMS Access Program are to mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors by:

- Prescribing and dispensing TIRF medicines only to appropriate patients, which includes use only in opioid-tolerant patients.
- Preventing inappropriate conversion between fentanyl products.
- Preventing accidental exposure to children and others for whom it was not prescribed.
- Educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose of TIRF medicines.

Effective March 12, 2012, Sold-to (corporate locations) making a direct purchase from the manufacturer are required to have a distributor registration in order to purchase and receive the following Fentanyl Citrate EQ Oral Trans sku's.

55253007430	FENTANYL CITRATE EQ ORAL TRANS 1200MCG30
55253007530	FENTANYL CITRATE EQ ORAL TRANS 1600MCG30
55253007030	FENTANYL CITRATE EQ ORAL TRANS 200MCG 30
55253007130	FENTANYL CITRATE EQ ORAL TRANS 400MCG 30
55253007230	FENTANYL CITRATE EQ ORAL TRANS 600MCG 30
55253007330	FENTANYL CITRATE EQ ORAL TRANS 800MCG 30

The registration is compliant for all of the SH locations associated with the Sold-to.

The Master Data Administrator (MDA) will access the **TIRF REMS Access Program** website https://specialtyhealthreporting.mckesson.com/InfoViewApp/logon.jsp every Monday of each week.

Enter the following information:
Username: teva_mwoods
Password: actavis0214 (all lower case)

NOTE: If you don't use this website, after 90 days the account will be deactivated. After six months, it will lock you out of the website. You will need to click account setup. Account reset walks you through to set up.

You will have access to the following tabs in the **TIRF REMS Access Program**:

- **Distributor Enrolled** – participants that are enrolled in the TIRF REMS Access program
- **Distributor Incomplete** – ignore this tab, not applicable
- **Distributor Deactivated** – customers opt out of the program

  - Click on **Corporate Categories>TIRF-REMS>Enrollment reports**. This will take you to the latest Distributor Reports and click on the Distributor Enrollment Detail, right click on document to **View Latest Instance or History.**

  - To save the report to your computer, click **Document** dropdown button and click **Save report to my computer as>excel, choose either open or save.** You might get a pop-up screen that it is blocked, **click here for options** and download file to your computer.

  - To print, click the print button be careful file is quite large.

  - Click on **Document List**, this will take you back to the **Document Listing** or click **Home.**

  - When you are finished using the website, click **log out.**

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The participants that were enrolled in the Actiq/Fentora program will be grandfathered into the TIRF REMS ACCESS program, they will be enrolled under the "distributor section" under the enrolled tab.

If the participant party opts outs, or does not register to participate in the TIRF REMS Access Program, you can locate the data under "Distributor" deactivated tab.

When the customer's registration is within 90 days of expiration, they will receive notice for renewal. Verify the new effective dates at the "distributor section" under the enrolled tab.

There are different scenarios for the REMS program but not limited to:

- If there is a new SP that is participating in the REMS program, you need to create a REMS registration from the valid date of the registration and the valid to is good for two years from that point that the registration was received.

- You need to verify that there is true SH's at the Sold-to level that orders controls. Each SH must be a entity of the Corporate Office. For example, American Health Packaging and Testpak are repackagers and they shouldn't be included in the REMS registration.

- If the Sold-to no longer participates in the TIRF REMS Access Program, you need to expire the REMS registration and add notes in the comment field that SP is no longer participating in TIRF REMS Access Program. There is no need to add exclusions since the REMS registration will be expired.

- If an order is placed for a participant that is no longer in the program, the order will go on license block. You can verify by SH location, that there was a REMS registration and the comment notes will show the reason for the expired registration.

- If there is an order that goes on license block, you will need to check the **Legal Control Issue Error Log Item** to view the reason for the block. It could block be either for DEA or State license and/or REMS registration. Look at the order and see what products are being ordered before going to the error log. If you notice it is Fentanyl products, than it is highly likely that it is due to a REMS registration issue.

- If the license block is for REMS, you need to search by SH location to see if there is a REMS registration and if there is, you need to check if the SH location was added to the registration.

- If the REMS registration is expired, you will need to contact the Customer Relations Administrator to handle.

NOTE: The external registration is "TIRFREMS" for all of the participating parties that have a REMS registration.

7. Health Identification Number (HIN)

If the HIN is being used, the Contracts Department need only submit the HIN. No additional documentation is required. The Master Data Administrator (MDA) will populate the current date in the "valid from" field and 12/31/9999 in the "valid to" field. On the ExpContrClass tab there is no need to include schedule numbers when creating a HIN, this field will be left blank. On the Customers tab, the MDA will need to add the customer account number and then accept the license under the Status tab. Input the SAP internal license number on the spreadsheet provided. Once all the HIN numbers have been created the updated spreadsheet needs to be forwarded to the Contracts Dept. if requested.

8. License blocks

The Master Data Administrator (MDA) will be responsible to ensure that pending sales orders on hold due to license violations are investigated. Once the investigation has been completed the MDA will take the appropriate action necessary to either release the sales order hold or notify the appropriate Order Entry representative regarding the necessary action required in order to update the license. If customer contact is necessary to obtain a valid license, the MDA will make an attempt to contact the customer to obtain a valid license. If the MDA is unable to obtain a valid license after contacting the customer, the MDA will notify the CRA/SAA and the CRA/SAA will contact the customer to obtain a valid license. For example, if the order went to License Block (VE31) and the MDA noticed that the customer cannot receive 2 and 2N on their license, the MDA would notify the CRA responsible for that account (and Order Processing, if necessary) that the customer is not able to receive the product they ordered. This usually happens when it is an EDI order or sample order. Note: For IMA customers, when an order is on VE31 and IMA block; and the MDA goes into the order to release it they will see a pop up message that states the order is on IMA block, do not make ANY changes. The MDA should back out of the order immediately and do not save any changes. The MDA must wait until the order is released from the IMA block before releasing the order from VE31 License Block; otherwise this will cause an error with the order. (IMA stands for Inventory Management Agreement, IMA customers are customers that have agreed to share confidential sales activity with Actavis in order to streamline their inventory.)

9. CII Schedule Drugs and SOMS blocks

SOMS – Suspicious Order Monitoring System (Of Control Drugs Substances)
The Master Data Administrator (MDA) will be responsible to ensure that pending sales orders on hold due to suspicious order violations (SOMS) are investigated. The MDA will execute VA05 to determine the value and priority of the orders blocked due to SOMS violations. A MDA will print the SOMS form in a PDF file. The SOMS form contains Class of Trade (COT) averages and customer allowable/order and customer allowable/month. NOTE: A SOMS form **should not** be re- printed in the next month for a SOMS form printed from a previous month. Column values only show the current month and will no longer show the previous month's values when printed later and will not be accurate to properly evaluation an order.

The MDA will review the SOMS form to determine if customer contact is necessary. If customer contact is necessary, the MDA will contact the customer. If necessary, the customer contact information can be obtained from the CRA responsible for the account. The MDA will contact the customer to determine if the order should be considered an 'order of interest'. If the customer decides to cancel or reduce the quantity, they will need to provide a reason for the reduction or cancellation. All orders that require additional analysis should be communicated to the appropriate CRA and CRA Manager.

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The following procedure is used to identify if the order is at or over the allowance Actavis gives the customer which will assist in determining the degree of analysis needed to release the order. Each order is evaluated and the best release code is applied to each order at that time.

Put the number that's in the "Order Quantity" column into the "Release Qty" column. Then, mathematically ADD the following columns "MTD Qty" plus the "Release Qty" to give you a total order quantity to date.

- The 'Pending Qty' column on the SOMS form shows other orders (not the one currently being viewed) that are on SOMS block for the same customer and product. This is to make the MDA aware of other order quantities in the system. The MDA should take the 'Pending Qty' into consideration when completing the analysis of the current order (the one being viewed).

- When releasing the order the MDA will use the most appropriate reason code for each order.

- If the "MTD Qty" plus the" Release Qty" is equal to or less than the "Customer allow/mth", then customer contact is not required.

- If the "MTD Qty" plus the "Release Qty" is greater than the "Customer Allow/mth", then further analysis is need and SOMS form will need 2nd signature from management.
  Some of the tools used during analysis:
  - Current month call log.
  - 852 & 867 data if available.
  - Past shipping history: Year over Year (YOY) or Year to Date (YTD) comparison.
  - Contact internal departments (i.e. Marketing, Demand Management, and CRA) to verify if they had information to assist in the analysis (i.e. Updated forecast, special orders, short-date, etc...).
  - Customer contact.
  - Controlled Substance Report – To update the report every day, open the current Controlled Substance Report and click **Start>All Programs>Business Explorer>Business Explorer (SAP BW 3)>Analyzer (SAP BW 3)**. At the top of the ribbon click **Add-Ins** and click the refresh button. You will get a pop-up screen to SAP Logon. Double click on SAP BW Production. You will get a pop-up screen to put your password. Make sure that Client – 300, User – your name, Password – enter password, Language, EN. Enter your password and press ok. You will get another screen called ZMKT_M01_Q0103: Trans. Click the execute button. The report will be updated and you will see the Last Refreshed date which will be today's date. Save excel file to V:\Sales Operations & Distribution\Customer Master\Licensing Department\SOMS Calls\Controls Sales History.
  - **Adding a new month to the Controlled Substance Report** – This is only done at the beginning of the month. First you need to **refresh query** and execute the report You need to go to **Cal/Year/Month** field name, do right **click on the field name** and go to **Select Filter Value**. You will get a pop-up screen called **Selection for Cal/Year/Month**. You need to take off the previous month (November 2012) and click the left blue arrow to move it to the left column called **Fixed Values** and then add the new current month (December 2012 or 12/2012), Click the right blue arrow to move it to the right column called **Selection and press ok**. The BW report will re-execute again showing the new month. **Adding new Material numbers for controls** – First you need to **refresh query** and execute the report. Right click on the **Material Number** field name and go to **Select Filter Values**. You will get a pop-up screen called **Selection for Material**. You need to add the new material number and/or NDC # for control substance only at the bottom on the **Fixed Values** column. Enter the new material number and click the right blue arrow to move it to the right column called **Selection and press ok**. At the end of the BW report, make sure the formula is copied several row for the new material numbers that were added.
  - When contacting the customer via email, the following verbiage should be used.
  - Subject: *"Company Name" Order(s) on Hold*
  - Body of email:
    - *Hi (Addressee(s)), in accordance with 21 CFR 1301.74, we are required to conduct independent analysis of orders prior to completing a sale to determine whether substances are likely to be diverted from legitimate channels. You have been contacted due to the fact that your order placed today has prompted further analysis based on a deviation in one of the following areas; unusual size, frequency, or pattern. In an effort to expedite the investigation process and mitigate any delays or inconvenience, we are requesting supporting information necessary to justify the fulfillment of the order in question.*

    - *PO#*
    - *NDC#, Mat#, QTY*

    - *Please note the entire order is on hold. Your quick response will ensure your entire order will be released in a timely manner.*

    Salutation

- The 'Release Qty' column on the SOMS form will need to be filled in by the MDA; this is the quantity that the MDA releases. Usually the 'Release Qty' is the same as the 'Order Qty', unless the customer requests to cancel the order or the MDA cancels the order with Management approval because the customer did not respond to the email sent by Master Data. ..

- If the customer decides to cancel the order, the MDA will request a reason for the cancellation of the order. Also, depending on the cancellation reason the MDA may forward the cancellation request to DEA Affairs for review. Please note: For IMA customers, if an increase is requested by the customer, the customer would need to be referred to the customer's CRA to have that request completed, and the increased order quantity will go through IMA again. (IMA stands for Inventory Management Agreement, IMA customers are customers that have agreed to share confidential sales activity with Actavis in order to streamline their inventory.)

- If the customer is contacted, the MDA will attach supporting documentation to the SOMS form which will include the customer contact name, phone number and/or email, reason for the increase, PO#, SD#, and date of order, and the SKU/Material number and description of the product released. If the same SKU/Material suspends again in the same month, the MDA will determine if the original resolution is appropriate for subsequent orders or if further analysis is needed.

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Actavis Pharma Inc.

US Order Management
Master Data / License Admin. Operational Procedure

PROCEDURE:	Create, Change or Create Listing/Exclusion for Controlled and Non-Controlled substance License		
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- If the customer decides to cancel the order, then the order may come off of SOMS violation. The MDA will need to execute the VA05 again to verify the order is not on the VA05 list.

- The MDA group should make an effort to get to know the customers and their customers. With that said, if the customer's response is a general response, i.e. increase due to new customers; it is recommended the MDA try to obtain the name, city, & state in which the new customer is located. Please know, the customer has the right to deny this request.

- The MDA will release and sign any orders that are 50 or less. These type of requests does not need management signature.

- The MDA will release and sign any order that is 50 or less on product launches or first time buys. These type of requests does not need management signature.

Once this SOMS form is confirmed and verified, the MDA will release the SOMS violation block.
Otherwise, the MDA will escalate the 'order of interest' (SOMS) to the DEA Affairs department for review and feedback. If DEA Affairs determines the 'order of interest' (SOMS) needs to be communicated to the DEA. Then DEA Affairs will contact the DEA.

B. Filing: Record Retention:

- Class 2 and 2N's are filed in a separate filing cabinet. The DEA requires all Class 2 and 2N's to be filed separately from the 3, 3N, 4 and 5. All SOMS are filed by the account name, account number, City and State, by most current date. If within the same day there are multiple SOMS, then the most current Sales Document number is filed on top.

   Also, there are four states Kansas, Kentucky, New York and Rhode Island which DO NOT allow CONTROLLED samples sent to ANY practitioners.

NOTE: If the customer requests to cancel the order or reduce a line quantity of a Class II (CII) order, an email of the change must be sent to Dept. Coordinator II in Gurnee.

C. License for One Time Customer:

The Master Data group will create a one-time Master Data template (shell) only once, as necessary. This shell will be used to create orders for one-time customers. A one-time customer shell will be used by order processing to create orders for situations where a permanent Master Data record is not needed, such as Tradeshows or Replacement Orders. A One-time customer shell SHOULD NEVER be used for any site order or control substance order. A Customer Master account must be set up in order to place these order types. These templates do not include entry of financial (company-level) data; as such, its usage should be restricted to free of charge orders (i.e., samples, literature etc.). If the one-time customer shell is used to generate a sales order, this record will supply basic customer master information and requires the order processing user to input key fields (i.e., name, address etc). The Master Data group will create the appropriate license for a one-time customer and link the license to the one-time ship-to customer's sales order.

D. Unlicensed Locations:

If a representative receives an order for prescription drugs for an unlicensed location, he/she must obtain the license of an individual who will accept responsibility for drugs being shipped to that specific location.
Such customers may include:
- Dialysis Centers
- Universities
- Health Organizations
- Clinics
- Humanitarian Aid
- Family Planning/Planned Parenthood

The account will then have the Facility's name in name 1 and the responsible doctor's name in name 2, the facility's address. The responsible doctor's state license will be attached at the account level.

In the event the request is submitted with a Mid-Level Practitioner's license, the Master Data Administrator (MDA) will verify that the Mid-Level practitioner is able to receive product by verifying their license on MedPro or checking with the manager of sample accountability. The Mid-Level Practioner's name will then be on name 2 of the account.

On occasion an order will come in for an unlicensed Actavis facility. When the order comes in it will go to License Block (VE31). In order to release this order from license block, a mock license will need to be created; the license will only be valid for one business day. Once the order has shipped the license will be expired. Only a State License with a single schedule of RX (no controls) will be created, the license number will typically be the first six characters of the city of the unlicensed facility or enough characters to be able to distinguish the location. For example if the order was going to Parsippany, NJ the license number would be PARSIP. The license will be attached at the account/Master Data level. If the order is for a TRADESHOW a mock license will be created as stated above except the license number will be "TRADESHOW".

On occasion we will receive an order from the FDA for Samples which the FDA does not have a State Board of Pharmacy license. If this is the case, you will need to create a 1 day State license with the external license number with the word FDA followed by the 10 digit telephone number (i.e. "FDA3123535863"). Expire the license once the DD# has been created.

E. Methamphetamine Control Act:

The Master Data Administrator (MDA) will create a valid DEA or State license for any Meth Act products. The DEA license is preferred; if DEA is not available the State license will be used. The system will display the DEA or State license on the packing slip for all Actavis products; this is done to be in compliance with State regulations.

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Actavis Pharma Inc.

US Order Management
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F. Indigent Accounts:

Dailies

These customers place orders on a daily basis and the account should be created in the physician's name, even if his office is located in a hospital or clinic. If the physician wants to ship goods to numerous locations, a Sold-To should be created for the primary location and Ship-To's should be created for the additional locations. All accounts are to be linked to the same state license even if the address does not match the license as long as this does not violate PDMA regulations. Note: The Sold-To address is usually the address that is on the physician's state license, but the physician may choose not to ship goods to the address listed on the state license, in this case the physician will choose another address as the Sold-To. If, at a later time, the physician wants to ship goods to the address listed on the state license, that account may be created as a Ship-To and linked to the existing Sold-To.
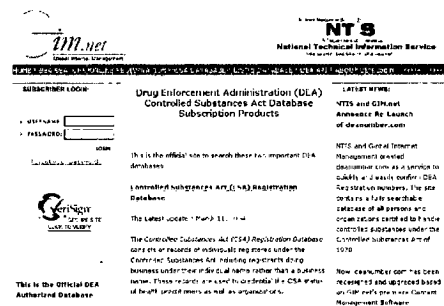
Trelstar and Indigents

Trelstar and Indigent orders are top priority and should be released as soon as possible following standard procedures.

G. PapSure Physician Address Changes:

NOTE: You do not need a license for PapSure orders, since the Material master record considers PapSure as an OTC product, therefore, the order should not be held up for a license.

H. R&D Research and Development:

This section may pertain to Clinical Research, Calibration and Marketing Demonstration Requests. In-house shipments for prescription items to facilities for research and/or development purposes do not require licensing. Please refer to "Unlicensed Locations" section for in-house shipments. Shipments going to outside companies require a valid State or DEA license. **Exhibit A - NTIS National Technical Information Services**

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US Order Management
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Exhibit A – NTIS continued…

DEA Number	Exp. Date	Company Name	State	Zip
AC0333734	8/31/2005	CITY PHARMACY INC	TN	37745
AT7665697	11/30/2006	SUSONG PHARMACY	TN	37745
BS0143850	2/28/2007	STUMM HARRY J MD	TN	37745
BP9389073	3/31/2007	PATTERSON, MARK DAVID MD	TN	37745
MM0349365	1/31/2005	MCMILLIAN, JEFFREY OD	TN	37745
MR0552081	4/30/2005	ROBBINS, MELISSA A FNP	TN	37745
MM0467426	3/31/2006	MORRISON, REBECCA A PNP	TN	37745
MP0551033	3/31/2006	PACE, NANCY L NP	TN	37745
MC0649472	8/31/2006	CARRINO, THOMAS PA	TN	37745
BW0300220	5/31/2004	WALGREEN CO	TN	37745
BT4966288	11/30/2004	THE MEDICINE SHOPPE	TN	37745
AC0401202	12/31/2004	REVCO DISCOUNT DRUG CTRS, INC	TN	37745
AR8276405	12/31/2004	REVCO DISCOUNT DRUG CTRS, INC	TN	37745
BF8029589	9/30/2005	FOOD CITY PHARMACY #605	TN	37745
BH2489032	10/31/2005	HOWARD'S PHARMACY	TN	37745
BR3339616	6/30/2006	RITE AID OF TENNESSEE INC	TN	37745
BG8518689	9/30/2006	GREENE COUNTY DRUG STORE, LLC	TN	37745

Select the hyperlink that matches the DEA information you are searching for.

m.net

NT.S
National Technical Information Service

Current Date: 3/15/2004   Data File Release Date: March 11, 2004

Drug Enforcement Administration (DEA) Datafiles –Both

Registrant Profile

for

CITY PHARMACY INC	
Address:	113 E CHURCH ST GREENEVILLE, TN 37745
State / Zip:	TN 37745
DEA Number:	AC0393734
Business Activity Code:	A
Drug Schedule:	22N 33N 4 5
Expiration Date:	8/31/2005

Print   Close

	Standard Abbreviations		
CRA	Customer Relations Administrator		
DEA	Drug Enforcement Administration		
MDA	Master Data Administrator		
MTD	Month to Date		
NTIS	National Technical Information Service		
PDMA	Prescription Dug Marketing Act		
SOMS	Suspicious Order Monitoring System (of Control Drugs Substances)		
YOY	Year Over Year		
YTD	Year To Date		

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Actavis	**Standard Operating Procedure**	**CS Compliance**
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1. REFERENCE TO QMS
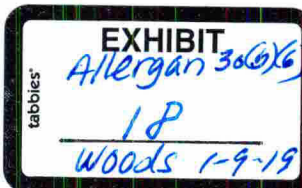
1.1.

2. PURPOSE

2.1. The purpose of this policy is the documentation and definition of the Controlled Substance Order Monitoring process based on the DEA requirements contained within 21 CFR 1301.74 and subsequent guidance letters detailing the responsibility of the registrant to design and operate a system to disclose suspicious orders of controlled substances and Listed Chemicals as well as the performance of customer due diligence both prior to the establishment of and during the business relationship.

3. SCOPE

3.1. This policy applies to the controlled substance ordering process under DEA Registration RW0237900, Actavis Pharma, Inc. 605 Tri-State Parkway, Gurnee, IL. Order processing and SOM administration is facilitated at the Parsippany, NJ Headquarters location.

4. DEFINITIONS

4.1. **Approved Customer** – A properly licensed and vetted supply chain partner with an established product purchasing relationship, to include controlled substances. These customers comprise the population monitored within the Controlled Substance Order Monitoring System.

4.2. **Controlled Substance Order Monitoring System** - a system designed to prevent product diversion through the disclosure suspicious orders of controlled substances. Such orders include but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. A Controlled Substance Ordering Monitoring System is comprised of the following elements; Customer Due Diligence, Electronic Monitoring, Review & evaluation, and Investigation process, as well as Notification to appropriate agencies.

4.3. **Controlled Substance Product** – A finished form commercially packaged drug or Listed Chemical product controlled within Schedule I, II, III, IV, or V of Section 21 Code of Federal Regulations, Part 1308.

4.4. **Know Your Customer (KYC) Process** – The process in which due diligence is performed with the goal of gaining insight into our prospective or established customers business model and making good faith efforts to ensure that buying patterns are aligned with appropriate use. Key elements of the KYC process include: Questionnaire(s), review of ownership, state and federal licensing, product utilization, on-going evaluation, site visits and investigations when necessary.

4.5. **Order of Interest (OI)** – A customer controlled substance order that pends within the electronic order monitoring system for exceeding the volume threshold for one of the established benchmarks. These orders will be investigated and if justified will be cleared

ΛΛ Actavis	Standard Operating Procedure	CS Compliance
	Controlled Substance Order Monitoring Policy	Page 2 of 7

and released. If an OI is determined to be suspicious will be reported to the DEA and appropriate state regulatory agency.

5. RESPONSIBILITY

5.1. Controlled Substance Compliance is responsible for the establishment and oversight of the Controlled Substance Order Monitoring Program, Know Your Customer function, order and account investigation, establishment of and maintenance of ongoing relationships with customer compliance personnel and regulatory authorities, as well as appropriate agency notifications.

5.2. Customer Service is responsible for initial customer due diligence, management of customer facing relationships, maintenance of accurate customer information, proactive communication of information pertaining to changes in customer ordering behavior to the appropriate internal stakeholders.

5.3. Order Management is responsible for initial controlled substance order review and release based on documented customer justification or tangible business rationale, escalation of orders that cannot be justified after initial analysis to appropriate investigative personnel, maintenance of effective communication with customer purchasing personnel and the proactive dissemination of information related to customer controlled substance utilization.

5.4. Global Security (Product Protection) is responsible for providing product specific expertise, communicating diversion trends, supporting investigational and vetting activities, and serving as order review/investigation contingency.

6. PROCEDURES

Controlled Substance Order Monitoring Requirements

6.1. Title 21, Code of Federal Regulations, Section 1301.74(b) requires that a DEA registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. Suspicious Orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Orders determined to be suspicious must be reported to the DEA upon discovery. DEA also requires that prior to distributing a controlled substance the registrant will make a good faith inquiry either with the DEA or appropriate state regulatory agency, to determine that the customer is registered to possess controlled substances. Beyond this requirement, case law expands further on the DEA position regarding due diligence. It is the DEA position that registrants are required to maintain adequate due diligence measures to protect against diversion and that the granting of a DEA registration signals only a proper application and the establishment of the required recordkeeping and security systems at the time of inspection and that the registration does not relieve a registrant of the responsibility to evaluate ongoing ordering behavior. Actavis will adhere to the requirements established within this policy to ensure that effective controls are maintained to prevent the diversion of controlled substances.

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Actavis	**Controlled Substance Order Monitoring Policy**	*Page 3 of 7*

The Actavis Controlled Substance Order Monitoring Program is based on a holistic approach comprised of the following elements:

- Know Your Customer – Due Diligence
  - Initial review and approval of customer
  - Ongoing review of current business relationships
- Electronic Monitoring and Review Process of Orders
  - Evaluation based on multiple parameters
  - Review of Orders of interest & customer outreach performed by dedicated order management team
- Order & Customer Investigation
  - Investigations & Site Visits conducted by CS Compliance
- Monthly Analytics
  - Trending analysis
- Large Volume Account Relationship Management
- Suspicious Order Reporting Process

Customer Due Diligence – Know Your Customer (KYC) Program

6.2. Actavis will conduct due diligence reviews on all new accounts. Periodic due diligence will be performed on existing accounts. Existing customer due diligence will be performed on customers considered to be large volume as well as customers who have had changes in business model, or have received or are under regulatory scrutiny. The Know Your Customer Process has been established as a method for screening potential business relationships and to better know our customers, ensuring that buying patterns are aligned with proper use.

6.3. The Know Your Customer (KYC) Program includes:

6.3.1. Collection and review of Customer Service/KYC Questionnaires and executed customer compliance acknowledgement form.

6.3.2. Review of ownership, state and federal licenses, and controlled substance and non-controlled substance utilization.

6.3.3. Review and approval of all new customers prior to the sale of controlled substance products.

6.3.4. Ongoing evaluation of purchases.

6.4. New Customer On-boarding

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6.4.1.   Actavis will perform due diligence on all prospective accounts. Actavis will determine whether proposed customers are fully licensed by federal and state authorities to handle controlled substances. Additional information including the types of products requested, forecast information, previous suppliers, controlled vs. non-controlled purchase ratio, and other suppliers, will be obtained and reviewed as part of the determination of customer acceptance. Site photographs and internet searches will also be utilized as a component of the due diligence process.

6.4.2.   Site visits and reviews will be conducted by Controlled Substance Compliance on all proposed controlled substances customers. Additional SOM program information and historical purchasing reports will be obtained for review. The prospective customer will provide a customer listing, by volume.

6.4.3.   Due Diligence Process

Prior to the sale of controlled substances to a new customer, the CS Compliance team in partnership with Customer service and Product Protection will perform an assessment consisting of the following actions:

6.4.3.1.   Internet Search – Searches will be conducted of open sources to include social media and industry related sites.

6.4.3.2.   Credit History Check – In coordination with Customer Service, a thorough credit analysis will be performed.

6.4.3.3.   Review of Ownership, State and Federal Licenses – A search will be conducted of state and federal regulatory agencies ensuring proper licensure, as well as any discipline such as suspensions, revocations or fines.

6.4.3.4.   DEA Website Search - A search will be conducted on the DEA Diversion website, www.deadiversion.usdoj.gov, for administrative, criminal or civil actions taken by the DEA against the registrant or their highest volume customers.

6.4.3.5.   CLEAR (Consolidated Lead Evaluation and Reporting) Record Search- A thorough check of public and proprietary records, and integrated web searching, including social network sites, providing information not found in public records will be performed for each prospective customer.

6.4.3.6.   Pharmaceutical Security Institute Inquiry – Search of all internal PSI databases and files, including:

6.4.3.6.1.   Counterfeiting Incident System (CIS)

6.4.3.6.2.   Open source index on pharma crime going back to 2002

6.4.3.6.3.   PSI archives (1991-2001)

6.4.3.6.4.   Prior inquiries file

ᴧᴧ**ᴧ** Actavis	**Standard Operating Procedure**	**CS Compliance**
	Controlled Substance Order Monitoring Policy	*Page 5 of 7*

6.4.3.6.5. Open source research checks include Lexis Nexis and PACER (US federal court records)

6.4.3.7. Sales Data Review and Analysis – An evaluation of the prospective customer's sales data will be completed for the controlled substance products requested. The following data will be reviewed;

6.4.3.7.1. Six months total historical sales for each product

6.4.3.7.2. Percentage of projected Actavis product sales

6.4.3.7.3. Top 50 customers for each product

6.4.3.7.4. Percentage of overall controlled v. non-controlled

6.4.3.7.5. Controlled substances purchased through other manufacturers. (Primary/Secondary)

6.5. Due Diligence – Existing Customers

6.5.1. Biennially, the Controlled Substance Compliance team will conduct a reassessment of each controlled substance customer. This assessment will include the completion of an updated compliance acknowledgement form, as well as a review of any changes within the compliance program and associated policies. Historical sales information for the previous six months will be requested as well as a current listing of their top 50 customers. Due diligence reviews may also be initiated as a result of adverse events or changes in customer business model.

6.6. Electronic Monitoring and Review Process of Orders

6.6.1. Actavis utilizes a proprietary system integrated within the company enterprise resource platform, SAP, for the purpose of monitoring controlled substance customer ordering behavior and identifying orders deviating substantially from the norm.

6.6.2. The system identifies customer orders that deviate substantially from their historic ordering patterns, size, class of trade, and customer thresholds.

6.6.2.1. The system checks every controlled substance order per line item placed by customers against the established benchmarks.

6.6.2.2. Product dosage unit thresholds are calculated for a specific customer based on historical product dosage unit data.

6.6.2.3. Multipliers are utilized to account for variability in customer buying behavior by specific customer and class of trade.

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6.6.3.   When a customer order line item is identified and placed on hold within the system as an order of interest, an instantaneous communication is sent to a trained Order Management SOM Specialist for review and the entire order is placed on hold.

    6.6.3.1.   Every order of interest undergoes a thorough review performed by SOM Specialist or Manager.

    6.6.3.2.   Orders that cannot be justified utilizing current historical ordering analysis or feedback from Marketing require further information from the customer.

    6.6.3.3.   Customers are engaged by the SOM Specialist or Manager to clarify and identify potential suspicious orders resulting from Orders of Interest.

    6.6.3.4.   All Orders of Interest requiring further investigation after contact with customers are escalated to the Controlled Substance Compliance Department for further investigation.

    6.6.3.5.   Controlled Substance Compliance investigations staff will perform a thorough investigation and will engage with customer compliance representatives with the objective of providing resolution.

    6.6.3.6.   Orders that are deemed as suspicious after investigation are presented for review by Senior Leadership including, Legal, Sales/Marketing, Operations & Compliance.

        6.6.3.6.1.   Immediately following leadership review suspicious orders are reported to the DEA as well as appropriate State Board of Pharmacy.

6.7.   Data Analytics

    6.7.1.   On a periodic regular basis Controlled Substance Compliance staff will perform prospective and retrospective analyses through the use of physical data. Data is utilized:

        6.7.1.1.   To guide and support decision making process in the order review process.

        6.7.1.2.   To guide and support customer vetting and investigations

        6.7.1.3.   To support trend analysis

    6.7.2.   On a Monthly basis, CS Compliance will review Charge-back data for key products with the objective of ensuring that pharmacy level customers are not purchasing excessive quantities of controlled drug products from multiple supplier sources.

Actavis (logo)	**Standard Operating Procedure**	**CS Compliance**
	Controlled Substance Order Monitoring Policy	*Page 7 of 7*

6.7.2.1.   Charge-back data provides a limited view of Actavis product usage only.

6.7.3.   On a quarterly basis Controlled Substance Compliance will review key controlled substance dosage unit purchase history for the top ten customers by volume.

6.8.   Large Volume Customer Review Process

6.8.1.   On an as-needed basis a team of designated personnel will review and make decisions regarding product volume increases for large wholesale distribution and chain pharmacy customers as they arise. The objective of the team is for the evaluation of requested needs for controlled product increases by a particular customer.

6.8.2.   The team is comprised of decision makers including:

6.8.2.1.   Customer Service

6.8.2.2.   Sales & Marketing

6.8.2.3.   CS Compliance

6.8.2.4.   Order Management

6.8.3.   Documented justification and team consensus is required for the approval of controlled substance product volume increases.

7. RELATED DOCUMENTS (Optional, if not used, state N/A - Delete green text)

7.1.

8. REFERENCES

8.1.   N/A

9. CHANGE HISTORY

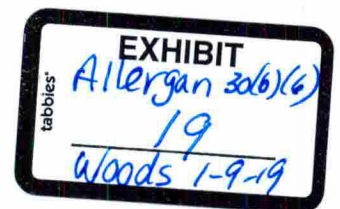| Livelink Workflow ID	Revision Number	Effective Date	Change Summary
		See effective date in header	1.

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Actavis

Suspicious Order Monitoring Program
Overview

As required by 21 CFR 1301.74 (b), Actavis Pharmaceuticals, Inc. operates an order monitoring system that discloses suspicious orders of controlled substances. Additionally, Actavis employs a "total SOM Program" that consists of customer vetting, order monitoring, and order investigation and disposition.

Actavis vets all prospective customers and requires the completion of a detailed questionnaire. Potential customers provide information relative to their business type, customer base (e.g. nursing homes, retail pharmacy locations, etc.), industry membership (e.g. HDMA), registrations (i.e. DEA and State Boards) and purchasing commitment. Actavis customers must order multiple product lines and cannot exclusively order controlled substances. Actavis's customers are primarily wholesalers, chains, distributors and mail order companies. Actavis does not sell direct to pharmacy locations.

Actavis utilizes an order monitoring component of SAP (a business management software) to evaluate a variety of order characteristics to intelligently determine whether a controlled substance order should be "suspended". These characteristics include order size, ordering frequency, ordering pattern, and similar attributes that assist in evaluating the likely "suspiciousness" of an order. Actavis's Customer Relations Department performs an initial review of the suspended order, at this point considered an "order of interest," and contacts the customer to request additional information/order justification.

Actavis's DEA Affairs Department is responsible for the investigation and disposition of controlled substance "orders of interest". These orders are thoroughly investigated and if substantiated by the customer, they are released within the SAP System and filled by Actavis's Gurnee, IL Distribution Center. If an order is deemed suspicious, the customer's order is cancelled and an investigation report is completed. All suspicious orders are reported to the DEA Chicago Field Office.

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Actavis

DEA Affairs
Controlled Substance Suspicious Order Monitoring: 'Order of Interest' Evaluation

PURPOSE

To define the requirements and establish guidelines for the evaluation of controlled substance orders of interest suspended by the Suspicious Order Monitoring System (SOMS) and report controlled substance suspicious orders to the Drug Enforcement Administration (DEA).

SCOPE

This policy applies to all Watson facilities registered with the Drug Enforcement Administration (DEA) to handle controlled substance products.

DEFINITIONS

Order of Interest: An order "pended" within the SOMS that is deemed "of interest" until it is investigated. Pended orders that are determined to be releasable must be approved by a member of Global Security & DEA Affairs.

Pend: Orders which have been blocked or stopped in real time by the SOMS because they exceeded the calculations and business rules established by Watson.

Suspicious Orders: Controlled substance orders which are of unusual size, deviate substantially from a normal pattern or are of unusual frequency and List I chemical orders which may involve extraordinary quantity uncommon method of payment or deliver or any other suspicious circumstance.

21 CFR 1301.74(b) states that "the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

21CFR 1310.05 (a) (1) states that "Each regulated person shall report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, as follows:
(1) Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this part."

RELATED DOCUMENTS

Title 21, Code of Federal Regulations, Section 1301.74(b)

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Controlled Substance Suspicious Order Monitoring: 'Order of Interest' Evaluation

Letters from the Drug Enforcement Administration dated September 27, 2006, February 7, 2007 and December 27, 2007

PROCEDURE

1.0   Pended Orders

1.1   Orders for all Watson customers are individually analyzed via an internal computerized statistical calculation to determine whether the order may be of unusual size, whether the order may deviate substantially from a normal pattern and/or whether the order can be associated with an unusual pattern or frequency. The statistical analysis is accomplished by a formula that uses a statistical algorithm and compares current orders from previous orders. This analysis will assign a "score" to each order based upon the analysis. This score will help to identify the level of suspicion of a pended order. An order will "pend" if any or all of these attributes are present to a statistically extent. These orders may be suspicious and must be investigated before shipping to the customer.

1.2   Customer orders with no previous history (new customer, new NDC, 1st time purchase of a GDC) will "pend" until there are purchases in two distinct months within the last six months. At that point it becomes part of the mathematical calculations of the model.

1.3   All "pended" orders will then be initially reviewed by the Customer Service department. The specific order information is presented on a series of (order/inventory system) review screens.

2.0   Order of Interest Evaluation

2.1   All orders will be "pended" in real time and the entire controlled substance order will "pend" until investigated and either cleared of suspicion or reported to DEA.

2.2   All orders will be initially investigated by the Customer Service Master Data Administrator.

2.3   The Master Data Administrator will gather relevant information to begin the review process. The following information will initially be considered:
    A.   The customer's order history with this drug.
    B.   Any "notes" in the customer file pertaining to the drug that has been "pended."
    C.   Whether other orders for this account have been "pended" before and what actions were taken on these pended orders.

2.4   After organizing this information, the Master Data Administrator will telephone or e-mail the customer. The Master Data Administrator will advise the customer *in general terms* of why the order pended.

2.5   The Master Data Administrator forwards all documentation to DEA Affairs personnel for review and evaluation. Orders are not released until written approval is granted by DEA Affairs personnel.

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DEA Affairs
Controlled Substance Suspicious Order Monitoring: 'Order of Interest' Evaluation

2.6 Some of the reasons that might allow DEA Affairs personnel to clear an order of interest include:
- Order error
- New and/or type of customers (requires confirmation)
- Verified increased market growth
- Market shortage
- New or different drug
- Different size or preparation
- Results of on-site review

2.7 If the order cannot be cleared based on the documentation provided by Customer Service personnel or if the customer has had previous orders pended and provided similar reasons, the reasons will be further investigated.

2.7.1 DEA Affairs and Customer Service management may host a "Customer Partnership" teleconference with the customer to initiate further discussion and gain additional information.

2.7.2 The DEA Affairs Security & Compliance Auditor may conduct an on-site visit to identify and examine the facility. Information to be considered may include buying groups, pharmacies, clinics, medical facilities and/or physicians. The on-site visit will seek to document any development that would legitimately cause an increase in the account's use of controlled substances. The results of the on-site investigation will be documented and the results of the investigation will be forwarded to DEA Affairs management for final review.

2.8 If DEA Affairs personnel determine that there is sufficient evidence in the file to conclude that the order is legitimate the entire controlled substance order will be cleared as an order of interest and released.

3.0   Reporting a Suspicious Order to the DEA

3.1 If an order cannot be cleared of suspicion, the DEA Affairs management will notify the local DEA Field Office in the area where the order has been placed, via telephone and then in writing via facsimile, that there is a suspicious order.

3.2 The order will be cancelled in its entirety and the account will be re-examined for possible closure.

3.3 Any conversations with any DEA personnel will be documented to include the name and title of the DEA employee and a summary of what was discussed.

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DEA Affairs
Controlled Substance Suspicious Order Monitoring: 'Order of Interest' Evaluation

4.0   Internal Audit Program

4.1   All orders that have been "pended" and "cleared" will be incorporated into Watson's internal audit program.

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Suspicious Order Monitoring Program
Customer Due Diligence Overview

Customer Due Diligence – Know Your Customer (KYC) Program

Actavis conducts due diligence reviews on all new accounts. Periodic due diligence are performed on existing accounts. Existing customer due diligence are performed on customers considered to be large volume as well as customers who have had changes in business model, or have received or are under regulatory scrutiny. The Know Your Customer Process has been established as a method for screening potential business relationships and to better know our customers, ensuring that buying patterns are aligned with proper use.

- The Know Your Customer (KYC) Program includes:
    - Collection and review of Customer Service/KYC Questionnaires and executed customer compliance acknowledgement form.
    - Review of ownership, state and federal licenses, and controlled substance and non-controlled substance utilization.
    - Review and approval of all new customers prior to the sale of controlled substance products.
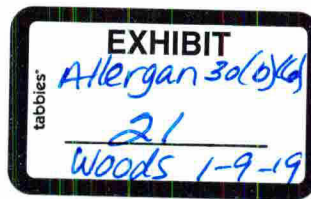   - Ongoing evaluation of purchases.
    - New Customer On-boarding

Actavis performs due diligence on all prospective accounts. Actavis determines whether proposed customers are fully licensed by federal and state authorities to handle controlled substances. Additional information including the types of products requested, forecast information, previous suppliers, controlled vs. non-controlled purchase ratio, and other suppliers, will be obtained and reviewed as part of the determination of customer acceptance. Site photographs and internet searches will also be utilized as a component of the due diligence process.

- Site visits and reviews will be conducted by Controlled Substance Compliance on all proposed controlled substances customers. Additional SOM program information and historical purchasing reports will be obtained for review. The prospective customer will provide a customer listing, by volume.

Due Diligence Process

Prior to the sale of controlled substances to a new customer, the CS Compliance team in partnership with Customer service and Product Protection will perform an assessment consisting of the following actions:

- Internet Search – Searches will be conducted of open sources to include social media and industry related sites.

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Suspicious Order Monitoring Program
Customer Due Diligence Overview

- Credit History Check – In coordination with Customer Service, a thorough credit analysis will be performed.
- Review of Ownership, State and Federal Licenses – A search will be conducted of state and federal regulatory agencies ensuring proper licensure, as well as any discipline such as suspensions, revocations or fines.
- DEA Website Search - A search will be conducted on the DEA Diversion website, www.deadiversion.usdoj.gov, for administrative, criminal or civil actions taken by the DEA against the registrant or their highest volume customers.
- CLEAR (Consolidated Lead Evaluation and Reporting) Record Search- A thorough check of public and proprietary records, and integrated web searching, including social network sites, providing information not found in public records will be performed for each prospective customer.
- Pharmaceutical Security Institute Inquiry – Search of all internal PSI databases and files, including:
  - Counterfeiting Incident System (CIS)
  - Open source index on pharma crime going back to 2002
  - PSI archives (1991-2001)
  - Prior inquiries file
- Open source research checks include Lexis Nexis and PACER (US federal court records)
- Sales Data Review and Analysis – An evaluation of the prospective customer's sales data will be completed for the controlled substance products requested. The following data will be reviewed;
  - Six months total historical sales for each product
  - Percentage of projected Actavis product sales
  - Top 50 customers for each product
  - Percentage of overall controlled v. non-controlled
  - Controlled substances purchased through other manufacturers. (Primary/Secondary)

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Actavis | DEA Affairs
Controlled Substance Customer Knowledge Policy (Know Your Customer)

PURPOSE

To define the requirements and establish guidelines for the evaluation, vetting, and relationship standards with controlled substance customers.

SCOPE

This policy applies to all Actavis facilities registered with the Drug Enforcement Administration (DEA) to handle controlled substance products and all facilities establishing regulated controlled substance business with customers.

DEFINITIONS

Customer:
Any persons (defined as any individual, corporation, government or governmental agency, business trust, partnership, association or other legal entity) that has, previously had, or seeks to have a relationship with Actavis Inc. (herein Actavis) for the purpose of purchasing any and all substances regulated by the Controlled Substances Act of 1970.

Audit:
A physical and/or documented evaluation performed by DEA Affairs and/or designated third party auditor for verification of compliance and conformance to applicable DEA regulations and/or corporate policies and procedures for all regulated activities.

Auditor:
An Actavis employee and/or consultant that possesses the education, training, and experience, or any combination thereof that enables them to perform audits of departments/facilities/customers engaged in DEA regulated activities, to ensure compliance with DEA regulations and/or corporate policies and procedures as applicable.

Suspicious Orders:
Controlled substance orders which are of unusual size, deviate substantially from a normal pattern or are of unusual frequency and List I chemical orders which may involve extraordinary quantity uncommon method of payment or deliver or any other suspicious circumstance.

21 CFR 1301.74(b) states that "the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

21CFR 1310.05 (a) (1) states that "Each regulated person shall report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, as follows:

(1) Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the

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Actavis | Controlled Substance Customer Knowledge Policy (Know Your Customer)

regulated person believes may indicate that the listed chemical will be used in violation of this part."

Pend: Orders which have been blocked or stopped in real time pending evaluation by DEA Affairs.

Vetting: The process in which DEA Affairs and/or authorized consultants evaluate a customer in regards to (but not limited to) compliance with all DEA regulations and/or corporate policies and procedures.

WHAT OTHER DEFINITIONS NEED TO BE ADDED?

RELATED DOCUMENTS

Title 21, Code of Federal Regulations, All Sections
Letters from the Drug Enforcement Administration dated September 27, 2006, February 7, 2007 and December 27, 2007

PROCEDURE

1.0   Customer Establishment (New)

1.1   Upon the request to purchase any controlled substance from a customer that has no previously established relationship with Actavis, Customer Service will notify DEA Affairs in writing.

    1.1.1   Customer Service will provide DEA Affairs with (at a minimum) the following:

        -   Customer Name/DEA Registration Number
        -   Location and contact information
        -   Order specifics (Product/Size)

1.2   Customer Service will "pend" the order until approval is/is not granted by DEA Affairs to ship the order. Orders not approved will be cancelled.

1.3   Upon receipt of the aforementioned information, DEA Affairs will request (in conjunction with Customer Service) a "partnership call" for the purposes of establishing a relationship with the customer.

    1.3.1   Prior to the "partnership call"; DEA Affairs and/or authorized personnel will perform an open source/business intelligence review of the company for the purposes of obtaining customer history, business practices, etc.

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Controlled Substance Customer Knowledge Policy (Know Your Customer)

1.3.2   During the "partnership call"; DEA Affairs and Customer Service will ascertain any relevant additional information regarding the potential customer and their practices. Additionally, specific information will be requested by DEA Affairs in terms of the potential customers business practices in regards to:

Compliance Overview:
- Team Structure
- Management Point of Contact

Suspicious Order Monitoring (SOM) Overview
- Due Diligence/Know Your Customer (KYC) Program
- Systematic Approach
- Order Review/Investigation and Disposition
- Associated Polices

Vetting/Distribution Limits Policy

1.3.3   Upon conclusion of the call, if warranted based on the above information, DEA Affairs will provide the customer with the following:

- Compliance Communication (Attachment A)
- Customer Questionnaire (Attachment B) - includes but not limited to:
  - Customer information on specified products
  - Customer profiles

NOTE: The order will remain in pending status until receipt and satisfactory review of the above.

1.4   Once determined to be a legitimate customer that meets the aforementioned requirements, the order will be released and the customer monitored through the established Actavis SOMS and KYC program.

2.0   Established Customers

2.1   Customers with previously established relationships will be periodically reviewed by DEA Affairs for the purpose of ensuring all aforementioned compliance communication is up to date.

2.1.1   If it determined that there is no current compliance communication, DEA Affairs will coordinate with Customer Service to establish a Point of Contact with the respective customer and the required communication will be requested.

2.1.2   Additional information may be requested from the customer at any time based on (but not limited to): an increase in orders pending in the SOMS program; a change in ordering history; the addition or subtraction of customers.

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Controlled Substance Customer Knowledge Policy (Know Your Customer)

2.1.3   On a periodic and/or as needed basis, DEA Affairs and/or an authorized consultant may conduct an on-site visit to identify and examine a customer's facility and operations.

3.0   **Customer Audits**

3.1   At any time and for any reason, DEA Affairs and/or authorized consultants may conduct an on-site visit to identify and examine the facility. Coordination will be handled in accordance with the identified Point of Contact

3.1.1 Information to be considered during audits may include and is not limited to:
- Customer (non-proprietary) information to include: site inspections, questionnaires, scorecard results; notes
- Due Diligence practices/policies/procedures
- SOMS procedures
   o   Review process; order disposition; required notifications

3.2   All information obtained will be maintained by DEA Affairs and periodically updated based on partnership calls/audits with the customer.

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1. REFERENCE TO QMS

1.1. N/A

2. PURPOSE

2.1. The purpose of this procedure is the documentation and definition of the Controlled Substance Order Monitoring process based on the DEA requirements contained within 21 CFR 1301.74 and subsequent guidance letters detailing the responsibility of the registrant to design and operate a system to disclose suspicious orders of controlled substances and Listed Chemicals as well as the performance of customer due diligence both prior to the establishment of and during the business relationship.
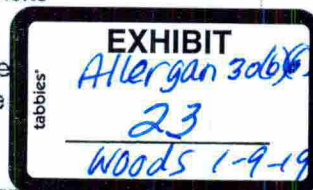
3. SCOPE

3.1. This procedure applies to the controlled substance ordering process under DEA Registration RW0237900, Actavis Pharma, Inc. 605 Tri-State Parkway, Gurnee, IL. Order processing and SOM administration is facilitated at the Parsippany, NJ Headquarters location.

4. DEFINITIONS

4.1. **Approved Customer** -- A properly licensed and vetted supply chain partner with an established product purchasing relationship, to include controlled substances. These customers comprise the population monitored within the Controlled Substance Order Monitoring System.

4.2. **Controlled Substance Order Monitoring System** - a system designed to prevent product diversion through the disclosure suspicious orders of controlled substances. Such orders include but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. A Controlled Substance Ordering Monitoring System is comprised of the following elements; Customer Due Diligence, Electronic Monitoring, Review & evaluation, and Investigation process, as well as Notification to appropriate agencies.

4.3. **Controlled Substance Product** -- A finished form commercially packaged drug or Listed Chemical product controlled within Schedule I, II, III, IV, or V of Section 21 Code of Federal Regulations, Part 1308.

4.4. **Know Your Customer (KYC) Process** -- The process in which due diligence is performed with the goal of gaining insight into our prospective or established customers business model and making good faith efforts to ensure that buying patterns are aligned with appropriate use. Key elements of the KYC process include: Questionnaire(s), review of ownership, state and federal licensing, product utilization, on-going evaluation, site visits and investigations when necessary.

4.5. **Order of Interest (OI)** -- A customer controlled substance order that pends within the electronic order monitoring system for exceeding the volume threshold for one of the

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established benchmarks. These orders will be investigated and if justified will be cleared and released. If an OI is determined to be suspicious will be reported to the DEA and appropriate state regulatory agency.

5. RESPONSIBILITY

5.1.   Controlled Substance Compliance is responsible for the establishment and oversight of the Controlled Substance Order Monitoring Program, Know Your Customer function, order and account investigation, establishment of and maintenance of ongoing relationships with customer compliance personnel and regulatory authorities, as well as appropriate agency notifications.

5.2.   Customer Service is responsible for initial customer due diligence, management of customer facing relationships, maintenance of accurate customer information, proactive communication of information pertaining to changes in customer ordering behavior to the appropriate internal stakeholders.

5.3.   Order Management is responsible for initial controlled substance order review and release based on documented customer justification or tangible business rationale, escalation of orders that cannot be justified after initial analysis to appropriate investigative personnel, maintenance of effective communication with customer purchasing personnel and the proactive dissemination of information related to customer controlled substance utilization.

5.4.   Global Security (Product Protection) is responsible for providing product specific expertise, communicating diversion trends, supporting investigational and vetting activities, and serving as order review/investigation contingency.

6. PROCEDURES

6.1.   Controlled Substance Order Monitoring Requirements

6.1.1.   Title 21, Code of Federal Regulations, Section 1301.74(b) requires that a DEA registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. Suspicious Orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Orders determined to be suspicious must be reported to the DEA upon discovery. DEA also requires that prior to distributing a controlled substance the registrant will make a good faith inquiry either with the DEA or appropriate state regulatory agency, to determine that the customer is registered to possess controlled substances. Beyond this requirement, case law expands further on the DEA position regarding due diligence. It is the DEA position that registrants are required to maintain adequate due diligence measures to protect against diversion and that the granting of a DEA registration signals only a proper application and the establishment of the required recordkeeping and security systems at the time of inspection and that the registration does not relieve a registrant of the responsibility to evaluate ongoing ordering behavior. Actavis will adhere to the requirements established within this policy to ensure that effective controls are maintained to prevent the diversion of controlled substances.

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6.1.2. The Actavis Controlled Substance Order Monitoring Program is based on a holistic approach comprised of the following elements:

- Know Your Customer – Due Diligence
  - Initial review and approval of customer
  - Ongoing review of current business relationships
- Electronic Monitoring and Review Process of Orders
  - Evaluation based on multiple parameters
  - Review of Orders of interest & customer outreach performed by dedicated order management team
- Order & Customer Investigation
  - Investigations & Site Visits conducted by CS Compliance
- Monthly Analytics
  - Trending analysis
- Large Volume Account Relationship Management
- Suspicious Order Reporting Process

6.2. Customer Due Diligence – Know Your Customer (KYC) Program

6.2.1. Actavis will conduct due diligence reviews on all new accounts. Periodic due diligence will be performed on existing accounts. Existing customer due diligence will be performed on customers considered to be large volume as well as customers who have had changes in business model, or have received or are under regulatory scrutiny. The Know Your Customer Process has been established as a method for screening potential business relationships and to better know our customers, ensuring that buying patterns are aligned with proper use.

6.2.2. The Know Your Customer (KYC) Program includes:

6.2.2.1. Collection and review of Customer Service/KYC Questionnaires and executed customer compliance acknowledgement form.

6.2.2.2. Review of ownership, state and federal licenses, and controlled substance and non-controlled substance utilization.

6.2.2.3. Review and approval of all new customers prior to the sale of controlled substance products.

6.2.2.4. Ongoing evaluation of purchases.

6.2.3. New Customer On-boarding

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6.2.4. Actavis will perform due diligence on all prospective accounts. Actavis will determine whether proposed customers are fully licensed by federal and state authorities to handle controlled substances. Additional information including the types of products requested, forecast information, previous suppliers, controlled vs. non-controlled purchase ratio, and other suppliers, will be obtained and reviewed as part of the determination of customer acceptance. Site photographs and internet searches will also be utilized as a component of the due diligence process.

6.2.5. Site visits and reviews will be conducted by Controlled Substance Compliance on all proposed controlled substances customers. Additional SOM program information and historical purchasing reports will be obtained for review. The prospective customer will provide a customer listing, by volume.

6.2.6. Due Diligence Process

Prior to the sale of controlled substances to a new customer, the CS Compliance team in partnership with Customer service and Product Protection will perform an assessment consisting of the following actions:

6.2.6.1. Internet Search — Searches will be conducted of open sources to include social media and industry related sites.

6.2.6.2. Credit History Check — In coordination with Customer Service, a thorough credit analysis will be performed.

6.2.6.3. Review of Ownership, State and Federal Licenses — A search will be conducted of state and federal regulatory agencies ensuring proper licensure, as well as any discipline such as suspensions, revocations or fines.

6.2.6.4. DEA Website Search - A search will be conducted on the DEA Diversion website, www.deadiversion.usdoj.gov, for administrative, criminal or civil actions taken by the DEA against the registrant or their highest volume customers.

6.2.6.5. CLEAR (Consolidated Lead Evaluation and Reporting) Record Search- A thorough check of public and proprietary records, and integrated web searching, including social network sites, providing information not found in public records will be performed for each prospective customer.

6.2.6.6. Pharmaceutical Security Institute Inquiry — Search of all internal PSI databases and files, including:

6.2.6.6.1. Counterfeiting Incident System (CIS)

6.2.6.6.2. Open source index on pharma crime going back to 2002

6.2.6.6.3. PSI archives (1991-2001)

6.2.6.6.4. Prior inquiries file

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6.2.6.6.5. Open source research checks include Lexis Nexis and PACER (US federal court records)

6.2.6.7. Sales Data Review and Analysis – An evaluation of the prospective customer's sales data will be completed for the controlled substance products requested. The following data will be reviewed;

6.2.6.7.1. Six months total historical sales for each product

6.2.6.7.2. Percentage of projected Actavis product sales

6.2.6.7.3. Top 50 customers for each product

6.2.6.7.4. Percentage of overall controlled v. non-controlled

6.2.6.7.5. Controlled substances purchased through other manufacturers. (Primary/Secondary)

6.2.7. Due Diligence – Existing Customers

6.2.7.1. Biennially, the Controlled Substance Compliance team will conduct a reassessment of each controlled substance customer. This assessment will include the completion of an updated compliance acknowledgement form, as well as a review of any changes within the compliance program and associated policies. Historical sales information for the previous six months will be requested as well as a current listing of their top 50 customers. Due diligence reviews may also be initiated as a result of adverse events or changes in customer business model.

6.3. Electronic Monitoring and Review Process of Orders

6.3.1. Actavis utilizes a proprietary system integrated within the company enterprise resource platform, SAP, for the purpose of monitoring controlled substance customer ordering behavior and identifying orders deviating substantially from the norm.

6.3.2. The system identifies customer orders that deviate substantially from their historic ordering patterns, size, class of trade, and customer thresholds.

6.3.2.1. The system checks every controlled substance order per line item placed by customers against the established benchmarks.

6.3.2.2. Product dosage unit thresholds are calculated for a specific customer based on historical product dosage unit data.

6.3.2.3. Multipliers are utilized to account for variability in customer buying behavior by specific customer and class of trade.

6.3.3. When a customer order line item is identified and placed on hold within the system as an order of interest, an instantaneous communication is sent to a

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trained Order Management SOM Specialist for review and the entire order is placed on hold.

6.3.3.1. Every order of Interest undergoes a thorough review performed by SOM Specialist or Manager.

6.3.3.2. Orders that cannot be justified utilizing current historical ordering analysis or feedback from Marketing require further information from the customer.

6.3.3.3. Customers are engaged by the SOM Specialist or Manager to clarify and identify potential suspicious orders resulting from Orders of Interest.

6.3.3.4. All Orders of Interest requiring further investigation after contact with customers are escalated to the Controlled Substance Compliance Department for further investigation.

6.3.3.5. Controlled Substance Compliance investigations staff will perform a thorough investigation and will engage with customer compliance representatives with the objective of providing resolution.

6.3.3.6. Orders that are deemed as suspicious after investigation are presented for review by Senior Leadership including, Legal, Sales/Marketing, Operations & Compliance.

6.3.3.6.1. Immediately following leadership review suspicious orders are reported to the DEA as well as appropriate State Board of Pharmacy.

6.4. Data Analytics

6.4.1. On a periodic regular basis Controlled Substance Compliance staff will perform prospective and retrospective analyses through the use of physical data. Data is utilized:

6.4.1.1. To guide and support decision making process in the order review process.

6.4.1.2. To guide and support customer vetting and investigations

6.4.1.3. To support trend analysis

6.4.2. On a Monthly basis, CS Compliance will review Charge-back data for key products with the objective of ensuring that pharmacy level customers are not purchasing excessive quantities of controlled drug products from multiple supplier sources.

6.4.2.1. Charge-back data provides a limited view of Actavis product usage only.

6.4.3. On a quarterly basis Controlled Substance Compliance will review key controlled substance dosage unit purchase history for the top ten customers by volume.

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6.5. Large Volume Customer Review Process

6.5.1. On an as-needed basis a team of designated personnel will review and make decisions regarding product volume increases for large wholesale distribution and chain pharmacy customers as they arise. The objective of the team is for the evaluation of requested needs for controlled product increases by a particular customer.

6.5.2. The team is comprised of decision makers including:

6.5.2.1. Customer Service

6.5.2.2. Sales & Marketing

6.5.2.3. CS Compliance

6.5.2.4. Order Management

6.5.3. Documented justification and team consensus is required for the approval of controlled substance product volume increases.

7. RELATED DOCUMENTS

7.1. N/A

8. REFERENCES

8.1. N/A

9. CHANGE HISTORY

Livelink Workflow ID	Revision Number	Effective Date	Change Summary
CD-33241174	00	See effective date in header	1. New Procedure

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| Document Name: **Controlled Substance Compliance Policy** | | |

| Number: **CSOP 001-165** | Revision Number: **00** | Effective Date: **26-May-2016** |

EXHIBIT
Allergan 30(6)(6)
24
Woods 1-9-19

1. REFERENCE TO QMS

1.1. N/A

2. PURPOSE

2.1. The purpose of this procedure is to document and describe the Actavis Corporate Controlled Substance Compliance Policy that has been established in accordance with the Controlled Substances Act (CSA) and the applicable sections of the Code of Federal Regulations (CFR) as they apply to the various DEA registered activities. This procedure describes the elements that comprise the controlled substance compliance program and clearly defines the roles and responsibilities of the Corporate Controlled Substance Compliance Department (CCSC), local site compliance function, and all relevant employees engaged in a controlled substance activity.

3. SCOPE

3.1. This procedure applies to all Actavis DEA Registered locations, employees, affiliates, and subsidiaries.

4. DEFINITIONS

4.1. **Controlled Substances Act** - Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain narcotics, stimulants, depressants, hallucinogens, anabolic steroids and other chemicals is regulated.

The CSA, established a closed system of controlled substance distribution requiring each entity in the distribution chain—that is, manufacturers, distributors, importers, exporters, pharmacies, practitioners, hospitals, etc., to be accountable for the drugs provided to the ultimate user (i.e., the patient). This is accomplished through a classification system of drugs based on their potential for abuse relative to their legitimate medical use. Such classification, or drug scheduling, triggers certain registration, quota, recordkeeping, reporting, and security requirements. The closed system ensures the accountability of these drugs from the manufacturer to the patient.

4.2. **Drug Enforcement Administration** – The agency within the US Department of Justice responsible for enforcing the controlled substances laws and regulations of the United States and bring to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States; and to recommend and support non-enforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets.

4.2.1. DEA Office of Diversion Control enforces the CSA and its implementing regulations governing legal controlled pharmaceuticals and regulated chemicals. DEA's mission with

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respect to legal controlled pharmaceuticals and regulated chemicals is complex. DEA seeks to prevent, detect, and eliminate the diversion of controlled pharmaceuticals and regulated chemicals from legitimate channels to illegal use, while ensuring their availability for legal medical, scientific, and industrial purposes

5. RESPONSIBILITY

5.1. Controlled Substance Compliance Policy Statement

5.1.1. The Actavis CS Compliance Policy Statement is as follows:

5.1.2. As a responsible manufacturer and a good corporate citizen to the communities where we conduct business, Actavis takes its responsibility to prevent drug diversion very seriously.

5.1.3. Our commitment to preventing drug diversion is critical. Throughout our manufacturing and supply chain processes, we employ safeguards that work to ensure legitimate patients receive our medicines, while minimizing the risk of diversion.

5.1.4. By engaging all Actavis team members on dangers of prescription drug abuse and the many things we can do as a company to safeguard against diversion, we achieve our mission of providing high quality, critical medicines while preventing abuse.

5.1.5. Controlled Substance Compliance is the responsibility of every Actavis team member. It is achieved through teamwork and commitment. The name Actavis represents the standard of quality to our employees, our customers and the communities in which we work.

5.2. Corporate Controlled Substance Compliance (CCSC) is responsible for ensuring (and assisting where appropriate) that all business functions engaged in a controlled substance activity implement the appropriate required compliance programs. CCSC is responsible for reviewing and auditing all related programs to ensure compliance with federal regulations, established policies & procedures, standards and guidelines.

5.3. Global Security is responsible for the implementation of the physical protection program and maintenance of effective controls designed to mitigate the opportunity for diversion in accordance with regulations set forth in 21 CFR 1301.72.

5.4. Senior management at each DEA registered location is responsible for ensuring that the site has sufficient and competent controlled substance compliance personnel commensurate with the scale of operation.

5.5. Each DEA registered location is responsible for the successful implementation of policies and procedures required to perform its functions effectively and in compliance with regulatory requirements.

5.6. The Corporate Controlled Substance Compliance and local compliance teams will assist each other in ensuring their compliance.

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6. PROCEDURE

Compliance Program Requirements

6.1. Regulatory Liaison and Policy Matters

6.1.1. While there are a number of individuals throughout the Actavis organization that have certain DEA related responsibilities and opportunities to interact with the DEA, Corporate CS Compliance has the primary and general responsibility for Actavis' relationship with the DEA. Corporate CS Compliance must be made aware of all contacts between any Actavis employee and the DEA, via prompt written notification.

6.1.2. Corporate CS Compliance is responsible for monitoring the regulatory landscape, interpreting regulatory changes with the assistance of groups such as Legal and Government Affairs, in the development of proactive strategies in anticipation of proposed rulemaking initiatives and translating regulations to the operations. The Corporate CS Compliance group is responsible for liaison with DEA Headquarters and units such as Liaison & Policy (ODLP), Regulatory (to include Import/Export), and Quota (ODE).

6.1.3. The site controlled substance compliance function has the primary responsibility for establishing and maintaining a positive and professional relationship with the local DEA office. It is within the scope of the site compliance representative's role to interact with the local DEA office regarding general matters pertaining to the normal course of business.

6.2. Recordkeeping and Reporting

6.2.1. All DEA registered site controlled substance compliance functions are responsible for establishing local procedures ensuring that recordkeeping obligations within 21 CFR 1304 are met. Policies shall be inclusive of:

6.2.1.1. General maintenance of records

6.2.1.2. Required Elements

6.2.1.2.1. Accurately reflect the actual movement of materials through legitimate channels of product lifecycle.

6.2.1.2.2. Readily Retrievable

6.2.1.2.3. Separately maintained for each registered activity

6.2.1.3. Material Accountability- Manufacturing (all stages) Transfer/Distribution, import/export, lab dispensing/usage, and disposal.

6.2.1.4. Procurement

6.2.1.4.1. DEA form 222 process administration

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6.2.1.4.2.   License verification

6.2.1.4.3.   Certification of available quota

6.2.1.5.   Required Inventories

6.2.1.6.   Continuing Records

6.2.1.7.   Electronic Records

6.2.1.8.   Record retention

6.2.2.   ARCOS Reports

6.2.2.1.   All DEA registered manufacturing and distribution location CS Compliance functions are responsible for the preparation and submittal of ARCOS (Automation of Records, Consolidated Ordering System) reports on a quarterly basis.

6.2.2.2.   The Corporate CS Compliance department will work closely with the sites and provide any necessary assistance, ensuring that these important reports are submitted accurately and in a timely manner.

6.2.3.   Year-end Reports (YER)

6.2.3.1.   All DEA registered manufacturing site CS Compliance functions are responsible for collaborating with the Corporate CS Compliance department in the preparation and submittal of the Year-End Activity Reports.

6.2.3.2.   The Corporate CS Compliance department will coordinate, prepare, and submit the final report prior to April 1st of each year.

6.2.3.3.   The site CS Compliance function will provide the corporate team with the required information in a complete and accurate manner facilitating successful timely submission.

6.2.4.   Theft & Loss Reports (DEA Form 106)

6.2.4.1.   The Corporate CS Compliance department is responsible for the submission of Theft & Loss reports to the appropriate DEA office.

6.2.4.2.   Site Global Security management is responsible for coordinating investigations into suspected theft or loss and will make initial notification to the appropriate DEA office.

6.2.4.3.   The site and Corporate CS Compliance departments will participate and support investigational efforts.

6.3.   Procurement Quota

6.3.1.   In accordance with established corporate policy, the Corporate CS Compliance department is responsible for facilitating the procurement quota process for all site commercial and product development activities.

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6.3.2. The Corporate CS Compliance department will collaborate with the appropriate internal stakeholders to obtain required information and sales/forecast data necessary for both annual and adjusted quota requests.

6.3.3. The DEA registered manufacturing site CS compliance function will ensure that local procedures are established for the management of quota for both commercial and product development purposes, ensuring that allocations are not exceeded and utilized for intended purpose.

6.4. Import & Export

6.4.1. In accordance with established corporate policy, the Corporate CS Compliance department is responsible for coordinating and facilitating the controlled substance import & export process.

6.4.2. The Corporate CS Compliance department will collaborate with the appropriate internal stakeholders to obtain required information required to execute compliant transactions in support of commercial, product development, and analytical activities.

6.4.3. The DEA registered manufacturing site CS compliance function will function as a conduit for the flow of information for the appropriate site activity and will ensure that transactions are documented and communicated to the Corporate CS compliance department in a timely manner ensuring that reporting obligations are achieved.

6.5. Regulatory Inspections

6.5.1. Corporate CS Compliance and site CS compliance function will ensure that policies mandating how the site will manage and handle a DEA inspection are implemented.

6.5.2. The site controlled substance compliance representative will be designated to manage all controlled substance audit activities. The controlled substance compliance representative will act as liaison with DEA investigators when they are on-site and afterwards.

6.5.2.1. The Corporate CS Compliance department will provide additional support and resources to the site inspection, including the gathering of information and documentation, providing overviews of compliance functions, corporate officer information as well as personnel resources to assist with or coordinate on-site activities.

6.5.3. The site controlled substance compliance representative will also designate a team of individual subject matter experts to support the various activities subject to audit. The team will be comprised of individuals responsible for certain areas, i.e. Security, Manufacturing, Quality Control, Quality Assurance, Warehouse, R&D. review and update procedures periodically.

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6.5.4. Corporate Controlled Substance Compliance will Coordinate annual mock DEA inspections of each DEA registered location. Inspections will encompass an accountability audit, record and report review, and security review.

6.5.4.1. Site controlled substance compliance and security representatives will conduct random and periodic internal audits of the daily controlled substance activities.

6.6. Suspicious Order Monitoring System

6.6.1. In accordance with established corporate policy, the Corporate CS Compliance department is responsible for establishing and maintaining the Suspicious Order Monitoring System as well as reporting those orders that are determined to be suspicious in nature.

6.6.2. The Controlled Substance Order Monitoring process is based on the DEA requirements contained within 21 CFR 1301.74 and subsequent guidance letters detailing the responsibility of the registrant to design and operate a system to disclose suspicious orders of controlled substances and Listed Chemicals as well as the performance of customer due diligence both prior to the establishment of and during the business relationship.

6.7. CS Compliance Internal Audit

6.7.1. In accordance with established corporate policy, the Corporate CS Compliance department is responsible for establishing and maintaining the Corporate Controlled Substance Audit Program.

6.7.2. The site CS Compliance function will participate in scheduled annual or "for cause" audits and collaborate with Corporate CS Compliance on the establishment and execution of corrective action plans or alternate remediation for any identified findings/observations.

6.7.3. The site CS Compliance function will establish an internal audit program for on-going periodic site compliance posture assessment

6.8. Training & Awareness

6.8.1. The Corporate CS Compliance department and site compliance function will collaborate on the development and delivery of annual focused compliance training.

6.8.2. The site CS compliance function will maintain and administer the controlled substance compliance new hire orientation program.

6.8.3. In conjunction with Corporate Communications, the Corporate CS Compliance department will administer and coordinate awareness & engagement activities via the *"It Starts With Me"* program.

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6.9.   Power of Attorney

    6.9.1.   The Corporate CS Compliance department is responsible for administering Power of Attorney, authorizing individuals at the registered locations to issue orders for Schedule I and II controlled substances via DEA form 222.

    6.9.2.   The Corporate CS Compliance department is responsible for training the designated site employees on the proper procedures for executing and Official Order form (222) prior to granting Power of Attorney.

    6.9.3.   The site CS Compliance function will ensure that an adequate number of appropriate individuals are designated as Power of Attorney to meet the needs of the operation.

7. RELATED DOCUMENTS

    7.1.   N/A

8. REFERENCES

    8.1.   N/A

9. CHANGE HISTORY

Livelink Workflow ID	Revision Number	Effective Date	Change Summary
CD-33285089	00	See effective date in header	1. New Procedure

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ADDITIONAL APPROVERS (Outside Livelink)

The below signatures have been obtained and are available on Quality Management System SharePoint site.

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I have reviewed this document and hereby approve it - Date and Signature	

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